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AN ASSESSMENT OF CLINICAL CHEMICAL SENSING TECHNOLOGY FOR POTENTIAL USE IN SPACE STATION HEALTH MAINTENANCE FACILITY

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ABSTRACT

A Health Maintenance Facility is currently under development for Space Station application that will provide capabilities equivalent to those found on earth. This final report addresses the study of alternate means of diagnosis and evaluation of impaired tissue perfusion in a micro gravity environment. Chemical data variables related to the dysfunction and the sensors required to measure those variables are reviewed. A technology survey outlines the ability of existing systems to meet those requirements. How the candidate sensing system was subjected to rigorous testing is explored to determine its suitability. Recommendations for follow-on activities are included that would make the commercial system more appropriate for Space Station application.

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SUMMARY

The objectives of this work were (a) to review chemical data variables desired for evaluation of impaired tissue perfusion, (b) to review sensors required for the evaluation (c) to survey and critique available state-of-the-art technology for satisfying the sensor requirements, and (d) to formulate a plan for design and evaluation of required sensors. In addition, a prototype test instrument for measurement of key data variables was assessed.

After consideration of previous work, it was felt that chemical data variables of particular importance include the blood gases as well as specific electrolytes, especially hydrogen and potassium. Other electrolytes and chemical compounds, such as lactate and glucose, may also prove to be valuable. Many off-the-shelf instruments are currently available for determination of most of the data variables identified above. However, for the most part these are geared toward quantitation of blood gases and pH or toward individual electrolytes or other chemical compounds. One instrument was identified which has the capacity for determination of blood gases and a variety of electrolytes in a single sample of whole blood. The instrument is the NOVA STAT PROFILE-1 manufactured by NOVA Biomedical Company. The instrument directly measures PO_2, PCO_2, pH, and hematocrit as well as electrolytes, including potassium sodium, calcium, and chloride. From the measured variables, several other variables are calculated, including hemaglobin saturation, oxygen content, and bicarbonate. The instrument is autocalibrating and provides outputs on a CRT and on hard copy.

The NOVA STAT PROFILE-1 was evaluated in-depth. Results obtained with the instrument were compared to those using accepted "Gold Standard" techniques. For this purpose, both human and canine blood were used. Human blood was obtained from patients in a dialysis unit, both before and after dialysis, from patients in the Intensive Care Unit (ICU) or Coronary Care Unit (CCU) of Fort Worth Osteopathic Medical Center, from patients in the ambulatory clinic of Texas College of Osteopathic Medicine and from normal volunteers. Canine blood was obtained during various cardiovascular and pulmonary perturbations designed to impede tissue perfusion or pulmonary gas exchange. Values for data variables obtained with THE NOVA STAT PROFILE-1 agreed well with those obtained using standard techniques; this agreement was applicable to blood gas variables, hematocrit, and electrolytes. The NOVA proved to be much more simple to use and calibrate than other techniques, provided rapid outputs, and exhibited a largely maintenance-free performance.

It is concluded that ion-selective technology, such as employed by the NOVA STAT PROFILE-1, satisfies the requirement for body fluid electrolyte sensors. It is also proposed that the NOVA instrument serves as a suitable prototype instrument for measurement of certain chemical data variables. It is felt that certain repackaging of the instrument can be made to better accommodate it in the Health Maintenance Facility.

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I. INTRODUCTION

The purpose of this document is to present in final form the work conducted under contract number NAS 9-17594. The overall thrust of this work was to (a) review and identify those chemical data variables which should be useful in diagnosis and evaluation of impaired tissue perfusion, (b) identify the sensors which will be required for measurement of these chemical data variables, where applicable, using ion selective technology (c) survey existing technology in order to ascertain whether the required sensors are currently available, and (d) formulate a plan for design and evaluation of the sensors. Since an instrument was identified which met the proposed requirements, extensive studies were performed to compare the performance of the prototype instrument with currently accepted, standard techniques for measurement of the defined data variables.

The present report presents the evaluation results of the prototype instrument in detail. Using human blood obtained under a variety of conditions, blood gases, hematocrit, and blood electrolytes were determined with the prototype instrument and with appropriate standard techniques. Analysis of the results of nearly 100 samples indicated a high correlation between values of data variables obtained with the two techniques. In addition, canine blood obtained under a variety of experimental conditions was used to assess the performance of the prototype instrument and to ascertain that data variables changed in the manner predicted during specific pathophysiological disturbances of cardiovascular or pulmonary function. The results of these experiments also demonstrated that the prototype instrument provided satisfactory and useful results. Finally, experiments were conducted in which multiple determinations on aliquots of the same blood sample were performed. These results showed a satisfactory level of agreement between multiple determinations.

II. BACKGROUND

A. Review of Required Data Variables.

Low cardiac output with a resulting reduction in tissue perfusion may lead to the generalized pathological condition known as circulatory shock and may result from any one of several causes (1,2,3). Thus, any factor that decreases the ability of the heart to pump blood into the circulatory system will lead to low tissue perfusion. Such factors include coronary artery disease, cardiac valvular disorders, cardiac infections, cardiac toxins, and cardiac electrophysiological impairments. However, even if the ability of the heart to pump blood is normal, low cardiac output and a reduced tissue perfusion may be caused by factors which reduce venous return and cardiac filling. These factors include a reduced blood volume (e.g., extensive hemorrhage, loss of body fluids through extensive burns, loss of body fluids by excessive vomiting or diarrhea, reduction in bodily fluid volume through excessive diuresis, or dehydration through reduced fluid intake). A reduction in venous return and cardiac filling may also result from factors which increase vascular capacitance (i.e., increase in vascular size through excessive vasodilation). An increase in vascular capacitance may result from a loss of vascular nervous tone such as in spinal injury, trauma, or vasodilator agents such as drugs or endogenous toxins. Finally, inadequate venous return and cardiac filling may result from an increased resistance to blood flow through the peripheral circulation. Increased resistance may be caused by an increased vasoconstriction, increased blood viscosity (such as occurs with increased hematocrit), or intravascular blood coagulation (disseminated intravascular coagulation or DIC).

In the well-equipped hospital setting, low cardiac output may be evaluated by use of a great variety of sophisticated invasive techniques. These include measurement of cardiac output itself along with such factors as pulmonary wedge pressure and central venous pressure. However, it is also highly feasible that low cardiac output and low tissue perfusion may be assessed by evaluation of chemical data variables in body fluids. The assessment of low tissue perfusion by evaluation of chemical data variables is primarily based on the fact that many cellular functions throughout the body tissues are active, oxygen-requiring processes and that oxygen is the most nearly flow-limited nutrient transported to the peripheral tissues by tissue blood flow. For this reason, any reduction in blood flow, regardless of its etiology, will lead to an impairment in many cellular processes. In many cases, this impairment in cellular function will be rapidly reflected by changes in the chemical composition of the venous drainage. While changes in the chemical composition of venous blood usually will provide the most readily accessible measure of inadequate tissue perfusion, the changes in blood composition may also be reflected by changes in the chemical composition of other body fluids.

A review of certain specific changes in body fluid composition known to occur as a result of low tissue perfusion is presented below:

(1) Changes in the partial pressure and concentration of oxygen in venous blood will almost always occur (1,2,4). Arterial oxygen partial pressure (PO_2) is normally about 100 mmHg; the arterial concentration of oxygen is normally about 20 volumes percent. As blood passes through the peripheral tissues, oxygen is extracted, and with a normal oxygen concentration in arterial blood and a normal resting rate of oxygen utilization by peripheral tissues, the average percent oxygen extraction by peripheral tissues is about 25%. Thus, normal mixed venous blood will have a PO_2 of about 40 mmHg and an oxygen concentration of about 15 volumes percent. If for any reason blood flow to the tissues is reduced, the peripheral tissues will attempt to satisfy their oxygen requirement by an increase in oxygen extraction from each unit of blood perfusing the tissue. Consequently, the PO_2 and oxygen concentration of venous blood draining the tissues will exhibit a reduction. It should be noted that in many cases of low cardiac output and low tissue perfusion, pulmonary gas exchange is not affected such that arterial PO_2 and oxygen concentration remain normal (5). In these cases, the reduction in venous oxygen reflects either an increased oxygen utilization by the tissues or a reduced tissue perfusion. A reduced venous oxygen concentration or PO_2 at rest generally implies a reduced tissue perfusion.

Assessment or arterial PO_2 or oxygen concentration is a somewhat more invasive technique and is more often used to assess the adequacy of pulmonary gas exchange. Thus, arterial PO_2 and oxygen concentration are characteristically reduced with low concentrations of oxygen in inspired air, in chronic obstructive pulmonary disease, in emphysema or similar diseases of the pulmonary membrane, and during reduced ventilation rates for any reason. Naturally, reductions in arterial PO_2 or oxygen concentration will also lead to reductions in venous values. In this regard, it may be noted that many changes in venous blood chemical composition brought about by impairments in pulmonary gas exchange may be very similar to changes in venous composition resulting from low tissue perfusion.

(2) Blood values for the partial pressure of carbon dioxide (PCO_2) and carbon dioxide concentration will also change with low tissue perfusion (4). Normal arterial PCO_2 is approximately 40 mmHg and carbon dioxide concentration is approximately 48 volumes percent. As blood moves through the peripheral tissues carbon dioxide diffuses from the cells into the capillary blood such that venous PCO_2 is approximately 45 mmHg and carbon dioxide concentration in venous blood is about 52 volumes percent. If tissue perfusion is reduced, increased amounts of carbon dioxide diffuse into each volume of blood passing through the tissue such that venous carbon dioxide values show a substantial increase.

As with the case of oxygen, it should be recognized that impairments of pulmonary gas exchange may also cause increases in arterial PCO_2 which will also be reflected by increases in venous PCO_2.

(3) Changes in hydrogen ion concentration (pH) will also occur with low tissue perfusion (4,5). These changes in pH are due primarily to the reduced delivery of oxygen to the tissues. Thus, when oxygen delivery to tissues is reduced, the tissues rely more heavily on anaerobic metabolism to meet their energy needs. A product of anaerobic metabolism is lactic acid, and as lactic production by tissues is increased, the pH of tissues and body fluids begins to fall. Although a reduction in venous blood pH is a known consequence of low tissue perfusion, it may also result if oxygen delivery is reduced because of impaired pulmonary gas exchange.

(4) As noted above, low tissue perfusion will result in an increased lactic acid concentration in blood (6,7). Most tissues of the body produce low levels of lactic acid even with adequate tissue nutrition. Some tissues such as myocardium extract lactate from blood at normal levels of myocardial oxygenation. However, all tissues, including myocardium, exhibit an increased lactic acid production during states of low oxygenation, such as occur with low tissue perfusion. Interestingly, the increase in lactate production with reduced oxygenation of the tissues is due not only to a shift from aerobic to anaerobic metabolism by the tissues, but also to the fact that hypoxia results in an increase in glucose transport across the cell membrane (8). Glucose is the substrate for anaerobic glycolysis, and this increase in the provision of glycolytic substrate along with an increase of activity of glycolytic pathways results in an even greater production of lactic acid. In addition to the increase in substrate provision by an increase in glucose transport across the cell membrane, hypoxia also results in an increased rate of glycogenolysis in most tissues (8). This increased rate of glycogen breakdown also provides a greater quantity of glucose for glycolytic pathways. Obviously, these events lead not only to an increased lactic acid production, but also to a substantial reduction in pH.

(5) Most conditions leading to a reduction in cardiac output and a general reduction in tissue perfusion are associated with increased sympathetic neural stimulation (1,2,3). This increase in sympathetic stimulation causes many measurable hemodynamic changes, e.g. increased heart rate, but also may lead to changes in the chemical composition of blood. For example, sympathetic stimulation promotes glycogenolysis, especially in liver and skeletal muscle. The increased glycogenolysis in liver causes a "dumping" of glucose into the circulating blood. For this reason, generalized low oxygenation, such as occurs with a low cardiac output, causes an early increase in blood glucose level

(9).

(6) Low tissue perfusion may also lead to changes in blood electrolyte concentrations. In normal physiological conditions, substantial concentration gradients of certain ions are maintained across the cellular membrane. These ion gradients are necessary for the normal excitability of cell membranes. Thus, sodium is actively "pumped" from the intracellular fluids to the extracellular fluids such that sodium concentration in extracellular fluids is much higher than that within the cell. Likewise, potassium ion is actively pumped from the extracellular fluid into the intracellular compartment, and potassium concentration within the cell is maintained at a much greater level than that in the extracellular fluid. These concentration gradients for sodium and potassium are present in most tissues but are especially prevalent in excitable tissues such as nerve and muscle. Calcium ion also exhibits a gradient across the cell membrane, and this gradient is due to an active membrane pump. Thus, calcium concentration in the extracellular fluids is maintained somewhat higher than within the cell. Certain ions such as chloride passes readily through the cell membrane and is passively distributed according to the electrical gradient existing across the membrane. Chloride distribution across the membrane is not the result of an active membrane pump. The active membrane mechanisms for maintaining ion gradients are oxygen requiring. As a result, when tissue oxygenation is impaired, the membrane pumps begin to fail, and the ion gradients across the membrane begin to diminish. For example, during poor tissue oxygenation, the intracellular level of sodium ion would begin to increase as extracellular sodium moves within the cell. Likewise, the extracellular level of potassium begins to increase as the high concentration of potassium within the cell causes a diffusion of potassium to the extracellular fluids and the membrane pump is unable to adequately transport this potassium back to the intracellular compartment. Since the extracellular level of potassium is normally very low while the intracellular potassium level is relatively high, inadequate tissue oxygenation with an impairment of the membrane pump rapidly leads to a detectable increase in extracellular potassium level (10). For this reason, it is felt that assessment of extracellular potassium concentration may be of particular importance in evaluating low tissue perfusion.

(7) Measurement of the hematocrit in blood may also be of value in assessing low tissue perfusion. Values for hematocrit, or actual hemoglobin concentration, would be extremely useful in deriving actual blood concentrations of oxygen and from measured values of PO_2. In addition, values for hematocrit give an easily accessible insight into changes in blood fluid volume. This is especially important since changes in fluid volume may occur rapidly during reductions in cardiac output with associated reduction in arterial pressure. In a normal adult, plasma volume

is approximately 3 liters, while interstitial volume is approximately 12 liters. Since water passes easily through the capillary membrane, the balance between plasma and interstitial fluid volumes is the result of a balance between certain forces acting to move water across the capillary membrane. One of these forces is the capillary filtration pressure. With reductions in arterial pressure associated with low cardiac output, capillary pressure is similarly reduced, and as a result, the forces acting on the capillary membrane shift from a slight filtration force to an absorption force tending to move water from the interstitial fluid into the vascular compartment (11). Consequent to this absorption of water from the interstitial spaces, a hemodilution occurs. It is well established that during conditions of circulatory shock, an early reduction in hematocrit can be seen as a result of this hemodilution (12). Interestingly, in late stages of progressive shock, as vascular deterioration begins to occur, fluid is once again filtered in excessive quantities from the vascular compartment into the interstitial fluids. As a result of this vascular deterioration, the early hemodilution gives way to a substantial hemoconcentration.

In the present work, particular emphasis was placed on review of available sensors for measurement of the variables outlined above. It was felt that since a multitude of works by a great many investigators have established that these data variables change in a predictable manner during low tissue perfusion, an effort to identify sensors for the detection of these data variables will show the greatest promise of success in attempting to evaluate low tissue perfusion by chemical techniques.

B. Review of Required Sensors and Available Technology.

This section will place primary emphasis on the review of the available sensors and technology for evaluation of those data variables outlined in the previous section. The available sensors for many of these data variables have been in use for great periods of time, and they, therefore, have a proven and accepted level of performance. Recent advances in these specific sensors more involve improvements or alterations in the associated instrumentation accompanying the sensor in order to facilitate its applicability. A concise review of the field is as follows:

(1) Partial Pressures of Blood Gases. Reliable sensors for determination of PO_2 and PCO_2 have existed for a number of years, and instrumentation incorporating these sensors are standard equipment in the clinical laboratory. Sensors for determination of PO_2 most commonly make use of the Clark electrode which contains a thin polypropylene membrane permeable to oxygen. After permeating the membrane, oxygen reacts with a platinum cathode at the electrode tip generating a current which is detected by appropriate circuitry. Determination of PCO_2 is

normally by a similar method. After permeating an appropriate thin teflon membrane, CO_2 reacts with pH-sensitive glass at the electrode tip and its inner silver/silver chloride electrode, thus generating an electrical potential. Most common instruments for determination of blood gas partial pressures contain both PCO_2 and PO_2 electrodes as well as a pH electrode. A sample of blood is injected into the instrument where it comes in contact with the 3 electrodes. The outputs of such an instrument are usually displayed on an LED meter. The most popular state-of-the-art instruments for measurement of blood gas partial pressures and pH are manufactured by the following companies:

Corning Instrument Company
Medfield, MA

Instrumentation Laboratory, Inc.
Lexington, MA

Radiometer Instrument Company
Dallas, TX

Certain manufacturers also make PO_2 electrodes in flow through cells or in catheter tip fashion for continuous monitoring of PO_2 using invasive techniques. Such companies include the following:

Hospex Fiberoptics
Chestnut Hill, MA

Coulbourne Instrument Company
Lehigh Valley, PA

(2) Blood Oxygen Concentration. Since the actual concentration of oxygen in blood varies with the hemoglobin concentration, the oxygen concentration cannot be derived from the PO_2 alone. However, state-of-the-art instruments are currently available for direct quantitation of blood oxygen concentration. The most popular is the hemoximeter. This instrument directly quantitates the hemoglobin concentration within the blood and the percent saturation of hemoglobin. From these 2 values, the oxygen concentration can be calculated (when 100% saturated, the blood oxygen concentration in ml/100ml of blood is equal to the hemoglobin concentration x 1.34 ml oxygen/gm hemoglobin). The most currently used hemoximeter is the model OSM-2 manufactured by Radiometer Instrument Company. Also available is a Co-oximeter made by Instrumentation Laboratories which measures hemoglobin and saturation spectrophotometrically.

Another instrument for direct measurement of blood oxygen concentration is the LEX-O_2-CON manufactured by Hospex, Inc. This instrument utilizes an oxygen-sensitive cell which electrically reduces oxygen to hydroxyl ions, generating a measurable current. This instrument is somewhat more difficult to operate than the hemoximeter or Co-oximeter and is also a

somewhat more fragile instrument than the hemoximeter. However, we have used both instruments in our laboratories and they provide equivalently reliable results.

(3) Blood pH. Electrodes for determination of pH are routine sensors in common pH meters as well as in many instruments which determine blood gases as pointed out above. In pH electrodes, hydrogen ion reacts with metal ions in the pH-sensitive glass at the electrode tip generating an electrical potential which is detected by associated circuitry. pH electrodes are routine in many chemical laboratories and are manufactured by a great variety of companies. Those used in conjunction with blood gas instruments have been pointed out above.

(4) Blood Glucose Concentration. Plasma glucose has been routinely measured in clinical laboratories using enzymatic methods and spectrophotometric determination. This enzymatic method has been modified by Beckman Instruments, Inc., to employ sensor technology. In the Beckman glucose analyzer, plasma is reacted with a glucose oxidase-catalase-ethanol solution. The hydrogen peroxide generated by the oxidation of glucose is decomposed by the catalase-ethanol mixture to form water and acetaldehyde. The rate of oxygen consumption during the oxidation of glucose is measured polarographically by an oxygen electrode similar to those described above. The rate of oxygen consumption is proportional to the glucose concentration.

This approach has been further advanced by Yellow Springs Instrument Company, Inc., who have utilized selectively permeable membranes to allow glucose access to enzymes immobilized by these membranes within an electrode assembly. In this "glucose electrode" the hydrogen peroxide produced by oxidation of glucose in the vicinity of a platinum electrode is measured amphometrically. This instrument is available from: Yellow Springs Instrument Co., Inc,; Yellow Springs, Ohio 45387.

(5) Blood Lactate Concentration. The Yellow Springs glucose analyzer can be readily modified to analyze plasma lactate. These modifications are (a) substitution of the lactate sensitive membrane in place of the glucose sensitive membrane, and (b) installation of immobilized L-lactate oxidase membranes to accomplish the oxidation of lactate in the vicinity of the platinum electrode. The lactate analyzer is also available from Yellow Springs Instrument Company, Inc.

(6) Blood Concentrations of Ions and Electrolytes. Electrodes have been developed for the potentiometric measurement of many ions, in addition to the hydrogen ion, by introduction of ion-selective membranes that are sensitive only to certain ions. They operate in a fashion similar to the glass electrode in its measurement of hydrogen ion concentration. Membranes utilized for ion sensitivity include selective glass membranes, membranes consisting of a crystal, and immobilized precipitate or a liquid

layer.

Clinically used ion-selective electrodes include those for potassium, sodium, calcium, and chloride ions. A sodium-sensitive glass has been developed that is insensitive to hydrogen ions and shows a selectivity for sodium over potassium of about 300 to 1. An electropotential is developed as the sodium ions undergo an ion exchange in the hydrated layer of the glass membrane. A potassium electrode incorporating a valinomycin membrane shows a selectivity for potassium over sodium of approximately 1000 to 1. This selectivity is due to the ion exchange cavities in the valinomycin which are about equal size to potassium ions. Similar approaches allow the selective determination of ionized calcium and chloride.

(7) Hematocrit. The cellular portion of whole blood (hematocrit) is determined routinely in clinical laboratories by centrification. Recently a new, compact approach using sensor-technology has been developed by Nova Biomedical. This approach uses the principle that electrical impedance of blood is inversely proportional to the number of red blood cells. Thus, by determining the impedance between 2 electrodes in a cell, the hematocrit can be determined. This technology is available from Nova Biomedical, Waltham, MA.

C. General Proposal for Prototype Instrument.

A prototype instrument which incorporates the latest state-of-the-art technology for determination of many of the above variables has recently been marketed by NOVA Biomedical, Inc. This instrument is the NOVA Stat Profile-1, and one of these instruments has been made available to us for evaluation by the manufacturer. We have performed extensive work in evaluating this instrument, and a complete description of the instrument is provided under the METHODS section below.

III. METHODS

A. Description of Prototype Instrument Tested.

When work under this contract was first begun, initial steps were taken to test individual ion-selective electrodes and to compare these results with standard techniques such as flame photometry. If ion-selective electrodes provided satisfactory results, the plans were to formulate a design by which important ion-selective electrodes could be incorporated into a single instrument for measurement of the respective ions in a single sample. Early in the progress of this work, during which time a survey of existing technology was being conducted, it came to our attention that one manufacturing company had recently marketed an instrument which not only provided measures of various ions using ion selective electrode technology, but also provided measures of many of the other important data variables identified in Section IIA. The Nova Stat Profile-1 manufactured by Nova Biomedical Company was marketed primarily for use in the surgical suite since the instrument was designed to provide rapid measures of key data variables of immediate interest to the attending physician. For the most part, these data variables are ones which are relevant to the cardiovascular and pulmonary status of the patient. We contacted Nova Biomedical and informed them of our interest in evaluating this instrument for possible use in the HMF. The company was generous in supplying us with one of their instruments on a loan basis in order that we may thoroughly evaluate it.

The following is a concise review of the instrument and its operation. A more thorough review of the instrument, its operation, its maintenance, and its technology is included in the Appendix, which is the user's manual for the Nova Stat Profile-1.

The Stat Profile-1 analyzer may be used with a variety of body fluids including serum, plasma, and whole blood. With appropriate dilution, the instrument may also be employed for analysis of urine. In addition to these fluids, the instrument may be used for analysis of expired gases. Using the instrument, samples are directly analyzed for the following variables:

PO_2

PCO_2

pH

Sodium

Potassium

Ionized Calcium

Hematocrit

From the directly measured results, certain variables are calculated. The calculated variables include the following:

Oxygen Saturation Level

Hemoglobin

Oxygen Content or Concentration

Bicarbonate Concentration

Total Carbon Dioxide Concentration

Base Excess of Extracellular Fluid

Standard Bicarbonate Concentration

Normalized Calcium

The principles for measurement of each of the directly determined variables is as follows:

(1) PO_2. The partial pressure of oxygen is measured using a standard Clark electrode as reviewed in section IIB.

(2) PCO_2. The partial pressure of carbon dioxide is also determined using a standard membrane tipped electrode as described above.

(3) pH. pH is measured using a hydrogen ion-selective glass membrane electrode as reviewed above.

(4) Hematocrit. Hematocrit is measured with an impedance electrode using the known electrical resistance of red blood cells in blood samples and corrected for the electrical impedance due to the concentration of sodium in the sample (sodium is by far the most concentrated ion in the blood).

(5) Ion Concentrations. The instrument tested was capable of measuring sodium, potassium, and ionized calcium concentrations. In order to measure the concentrations of these ions, the NOVA Stat Profile-1 uses ion-selective electrode technology as described above.

The Stat Profile-1 employs a microcomputer which derives certain calculated values based on the actual directly measured values. Certain features of the derived values are as follows:

(1) Temperature Correction. All data variables are measured at a temperature of 37^{o} centigrade. If a patient's body temperature is different from 37^{o} centigrade, the actual body temperature may

be entered into the microcomputer via a key pad. Measured values for pH, PCO_2, and PO_2 are then corrected to the actual patient's body temperature.

(2) Ionized Calcium Normalized to pH 7.4. Since the activity and concentration of ionized calcium in whole blood, plasma and serum is pH dependent, the value for ionized calcium measured is corrected to a pH of 7.4 if the measured pH is different from this value. Thus, this normalized calcium value represents what the ionized calcium concentration would have been if the initial pH was 7.4.

(3) Oxygen Saturation. Oxygen saturation is defined as the percent of the hemoglobin in blood that is actually bound with oxygen. In order to calculate the oxygen saturation in a blood sample, the microcomputer uses the actually measured PO_2 and employs this value in an equation representing a normal oxygen-hemoglobin dissociation curve.

(4) Hemoglobin Concentration. The concentration of hemoglobin in the blood is calculated from the measured hematocrit. In calculating hemoglobin it is assumed that the hemoglobin concentration (grams/100 ml blood) is equal to the measured hematocrit (%) divided by 3.

(5) Oxygen Content. Oxygen content is the total amount of oxygen contained in a given volume of whole blood, including dissolved oxygen (which amounts to only a small portion of the total oxygen) and oxygen bound to hemoglobin. The equation for calculating oxygen content assumes a value of 1.39 ml of oxygen per gram of hemoglobin. It is noted that in most cases the hemoglobin concentration based on the measured hematocrit value is a valid assumption. However, if hemoglobin is directly measured by a separate methodology, the actual measured hemoglobin value can be entered, and the oxygen content calculated will be based on the actually measured hemoglobin.

(6) Bicarbonate Concentration. Bicarbonate concentration is calculated from the measured values of pH and PCO_2 using the Henderson-Hasselbach equation.

(7) Total Carbon Dioxide Content. The total carbon dioxide content includes both the carbon dioxide dissolved in plasma and the carbon dioxide combined as bicarbonate. The total carbon dioxide content is calculated as the sum of bicarbonate plus the PCO_2 times the solubility coefficient for carbon dioxide.

(8) Base Excess of Blood. Base excess of blood is defined as the number of mmoles of strong acid or base needed to titrate 1 liter of blood to a pH of 7.4 at 37^{o} centigrade when the PCO_2 is held constant at 40 mmHg. The microcomputer of the Stat Profile-1 calculates the base excess of blood from the measured values

for hemoglobin concentration, pH, and the calculated value of bicarbonate concentration.

The instrument contains a reagent pack with reference and calibration reagents for pH and other ions. The reagents for the ions consist of standard solutions of the ions at least 2 different concentrations. The reagents are totally inorganic in composition. In addition to the reference solution and the 4 standard solutions, the reagent pack contains a flush solution as well as a waste bottle for disposal of waste. In addition to these reagents, the instrument contains 2 tanks of calibrating gas for calibration of the blood gas electrodes. These tanks are of the small E size variety. The instrument contains an internal barometer used in measurements of gas partial pressures. Its range is 450-800 mmHg. The instrument performs a 1 point calibration after every sample analysis and a 2 point calibration every 2 hours. The reagent pack contains all fluids necessary for analysis of 300 samples. As now designed, all reagent solutions are contained in rigid plastic bottles and flow of reagents is caused by an electrical pump. The instrument also uses the electrical pump to pull the sample fluid through an external inlet port. For each sample analysis, 0.250 ml of sample fluid is loaded into the electrode compartment.

As now designed, the outputs of the instrument are displayed on a CRT and are printed on hard copy. The CRT also displays user information. The instrument also has the capacity for addition of a modem for remote service contact and diagnostics. The instrument is controlled by a key pad mounted on the front face, and the is extremely user-friendly. Our experience has been that only a short period of training and familiarization is required for its operation.

The physical dimensions of the Stat Profile-1 are as follows: Height = 19 inches, width = 22 inches, depth = 22 inches, weight with full reagent pack = 135 pounds.

B. Gold Standard Techniques.

For evaluation of the prototype instrument blood samples were analyzed with the instrument and the results were compared to results obtained upon analysis of aliquots of the same samples using accepted "Gold Standard" techniques. The particular Gold Standard technique which was employed depended upon the data variable of interest. The standard used for each of the data variables are reviewed below:

(1) Blood Gases and pH. The values for PO_2, PCO_2, and pH obtained using the Stat Profile-1 were compared to those using the Corning Model 175 blood gas analyzer. The Corning instrument uses standard oxygen, carbon dioxide, and pH electrodes and is a commonly accepted instrument existing in many clinical laboratories.

(2) Hemoglobin Concentration, Hemoglobin Saturation, and Oxygen Content of Blood. The values for these variables are not directly measured by the Stat Profile-1 but are derived from other directly measured values. The derived values were compared to directly measured values obtained by use of a Radiometer OSM-2 hemoximeter. This also is a commonly used and accepted instrument for determination of these data variables.

(3) Hematocrit. The hematocrit measured by quantitation of the electrical impedance of blood by the Stat Profile-1 was compared to the hematocrit direct measured by the centrifugation technique. For this purpose, capillary tubes were filled with aliquots of the blood samples, and the red blood cells were centrifuged using a Clay-Adams hematocrit centrifuge.

(4) Blood Concentration of Sodium and Potassium Ions. The concentrations of these ions as determined using ion selective electrode technology with the Stat Profile-1 were compared to values obtained using the flame photometric technique. For this purpose an Instrumentation Laboratories flame photometer was employed.

(5) Concentration of Ionized Calcium. Values for ionized calcium were not obtained by a standard technique. Rather the values for ionized calcium obtained using selective electrode technology with the Stat Profile-1 were compared to values for total blood calcium obtained using a the ACA standard colorometric technique. This colorometric technique is routinely employed by our Toxicology division of the Department of Pathology and Toxicology. It provides a value for total blood calcium, including both ionized and bound calcium. The portion of total calcium which is in the ionized form amounts to about 45-50% and is very consistent from individual-to-individual (13). Therefore, a comparison of ionized calcium with total calcium provided a reasonable measure of the reliability of the Stat Profile-1 in the measurement of blood ionized calcium.

(6) Concentration of Blood Bicarbonate. Blood bicarbonate concentration with the Stat Profile-1 is calculated for measured values of pH and PCO_2. These values were compared to those obtained using the Corning Model 175 blood gas analyzer. The Corning instrument also derives bicarbonate from measured values of pH and PCO_2.

C. Protocols.

Analyses were performed on both human blood and canine blood. The general protocols are described below.

(1) Human Blood Samples. In order to get a great variety in the values of data variables measured, both arterial and venous blood samples were drawn from a variety of human subjects. In all

cases, an aliquot of the blood sample was drawn in a heparin-lined vacutainer (green top), and another aliquot was drawn in a vacutainer for blood clotting (zebra top). The heparinized sample was used for analysis in the NOVA Stat Profile-1 as well as for blood gas, pH, hemoglobin concentration, percent hemoglobin saturation, oxygen content, and hematocrit using Gold Standard techniques. The sample that was drawn in the zebra top vacutainer was allowed to clot, and the serum was used for analysis for potassium, sodium, and calcium. All analyses were performed within 20 minutes of blood withdrawal. Analyses on the heparinized aliquot were performed in the Department of Physiology at Texas College of Osteopathic Medicine, while ion analyses on the serum aliquots were performed by the Department of Toxicology at Texas College of Osteopathic Medicine.

The human blood samples analyzed included 19 samples from the ambulatory care clinic at Texas College of Osteopathic Medicine, 50 samples from the renal dialysis unit (25 of these were from patients immediately prior to dialysis and 25 were from those same patients immediately following dialysis), 9 samples from the ICU/CCU of Fort Worth Osteopathic Medical Center, and 14 samples from normal human volunteers. Of the patients in the ambulatory care unit and the ICU/CCU, patient diagnoses included chronic obstructive pulmonary disease, myocardial infarction, cardiac arrhythmias, theophylline toxicity, and noncompliance with diuretic drug therapy. The normal volunteers included professional and student workers in the Department of Physiology with ages ranging from 20-45 years. All procedures using human blood were approved by the Texas College of Osteopathic Medicine Institutional Review Board (IRB), and signed Patient Consent Forms were obtained for all subjects.

(2) Canine Blood Studies. In addition to analyses on human blood, a total of 56 analyses were performed on samples of canine blood. Canine blood has a composition almost identical to that of human blood, thus making the results applicable to the human. These studies on dogs were performed for 2 general purposes. First, cardiovascular and/or pulmonary perturbations could be applied to the anesthetized animal in order to produce wide variations in measured data variables. Such a wide variation in values added credence to the comparison of results obtained with the Stat Profile-1 instrument and Gold Standard techniques. Second, by application of controlled cardiovascular and/or pulmonary perturbations, we felt we could gain added insight into whether or not the selected data variables changed in the direction predicted. Thus, the results of these studies gave initial support for the applicability of these selected data variables in evaluation of cardiovascular or pulmonary impairments.

In animal studies, arterial and/or venous blood samples were withdrawn under control conditions, during the course of a specific perturbation, and during a recovery period. Perturbations included (a) hyperventilation caused by increasing

respiratory rate from a control value of 12/min to 18/min, (b) hypoventilation caused by a reduction in respiratory rate from a control value of 12/min to 6/min, and hypovolemia caused by controlled hemorrhage. In addition, further experiments were performed on dog's blood in order to examine the consistency of measurements made with the Stat Profile-1. For this purpose, 6 different canine blood samples were employed, and each sample was analyzed 4 consecutive times within a period of 15-16 minutes.

D. Data Analysis.

All data variables obtained from the NOVA Stat Profile-1 were compared to those using Gold Standard techniques using a linear regression analysis. For this purpose, it was assumed that the Gold Standard result was an absolutely accurate and independent variable (X-axis) and the results from the Stat Profile-1 was the dependent variable (Y-axis). The regression of Y on X was then obtained for all human blood samples analyzed using the least mean squares technique, and a regression coefficient (r) was calculated. To test whether the slope of the linear regression obtained was different from a value of 1 (i.e. that values obtained with the Stat Profile-1 were different from those obtained using Gold Standard techniques), the following equation was employed to calculate t-value (14):

$$t = \frac{\text{Slope} - 0}{\sqrt{\text{S.E. of Slope}}}$$

(degrees of freedom = n-2)

A P value > 0.05 was accepted as an indication that the regression was not different from 1, i.e. it was not different from identity.

In addition to obtaining a linear regression for all human blood samples, regression analyses were also performed on certain subsets of data. Specifically, regression analyses were performed on human blood obtained from the renal dialysis unit. One regression was performed on blood obtained immediately prior to dialysis, while another regression analysis was performed on blood obtained immediately after dialysis. Since some chemical data variables were altered substantially by dialysis, a comparison of predialysis and postdialysis regressions of all data variables gave insight into mutual interactions or interference of one chemical constituent upon another. For example, the concentration of potassium ion was found to be altered substantially by dialysis. In this case, if the regression of X on Y for sodium ion did not change from the predialysis blood to the postdialysis blood, the results would indicate that changes in potassium ion do not affect the reliability of the instrument (i.e. ion-selective electrode technology) in determination of sodium.

In many cases, the concentration of a chemical constituent was not found to vary greatly among the many blood samples analyzed. In such cases, linear regression analysis did not produce reliable results. Thus, in these cases the mean values of that chemical component as determined with the Stat Profile-1 was compared to the mean value determined with the respective Gold Standard technique using Student's t-test for unpaired data (15). In these cases, a P value > 0.05 indicated that the mean values were not significantly different.

For statistical analysis of canine blood samples, statistical techniques similar to those for human blood were employed. However, the flame photometric technique for analysis of ions in canine blood was not employed.

IV. RESULTS

A. Comparison of Prototype and Standards.

This section will present the results obtained both in studies of human blood and in studies of canine blood. The results presented here are displayed in figure form as well as in tabular form in the C and D sub-sections of the Results section.

(1) Comparison of Prototype and Standards in all Human Blood Samples. Blood samples were analyzed in 92 human blood samples using both the Stat Profile-1 and standard techniques. A comparison of values between the two techniques among the total set of human blood samples is presented here.

Figure 1 shows the linear regression of values for PO_2 determined by the NOVA Stat Profile 1 on values obtained using the Corning Blood Gas Instrument. The solid line is the calculated regression of Y on X while, the dashed line represents the line of identity (i.e. the line upon which all points would fall if the NOVA determinations were exactly the same as the Corning determinations). The actually determined equation for the linear regression of Y on X is shown at the top of the Figure is as the calculated regression coefficient (r). Table 1 shows all values determined by both the NOVA and the Standard technique. The column on the left (ACC #) is the accession number for each sample. The column of numbers of the far right shows the absolute difference between the value obtained by the NOVA instrument and by the Standard instrument. The mean PO_2 for all blood samples as determined by the NOVA instrument was 76.5 mmHg, while that determined by the Corning was 77.3 mmHg. There was no significant difference between these two means ($P>0.05$). It can also be seen in Figure 1 that the regression of the NOVA values on the Corning values was extremely close to unity and that the regression coefficient was extremely high (an r value of 1.000 would indicate that all points fell on the same line). In the case of PO_2, the slope of the linear regression of Y on X was not significantly different from a value of 1.

Figure 2 shows the linear regression of Y on X for PCO_2, and Table 2 shows all values of PO_2 determined by both the NOVA Stat Profile-1 and the Corning blood gas instrument. Among all blood samples, the mean PCO_2 as determined by the NOVA instrument was 42.4, mmHg while that determined by the Corning instrument was 40.0 mmHg. There was no statistically difference between these two values. As can be seen in Figure 2, the regression of Y on X was very similar to the line of identity, and the coefficient for this regression was extremely high. There was no significant difference between the actually determined slope of the regression and the theoretical line of identify.

Figure 3 shows the results obtained among the total number of blood samples when determining pH by the NOVA instrument and by the Corning instrument. Table 3 shows the individual value for all blood samples. Among all blood samples, the mean pH

determined by the NOVA instrument was 7.339, while the mean value determined by the Corning was 7.346. There was no significant difference between these two means. Furthermore, as can be seen in Figure 3 the regression of Y (the NOVA values) on X (the Corning values) was very close to the theoretical line of identify. Again, the coefficient for this linear regression was extremely high. Also as seen in the case of PO_2 and PCO_2, the slope of the linear regression for pH was not statistically different from the theoretical value of 1.

The results of obtained in all blood samples for hematocrit (Hct) are shown in Figure 4 and Table 4. Among all blood samples, the mean hematocrit as determined by the NOVA instrument was 37.03%, while that determined by the centrifugation technique was 35.73%. There was no statistically significance difference between these two means. Furthermore, as seen in Figure 4 the linear regression of Y on X exhibited a very high regression coefficient and was similar to the theoretical line of identify. There was no statistically difference between the slope of the experimentally determined regression and the theoretical value of 1.

Figure 5 show the results obtained from the total number of human blood samples for potassium ion concentration. The individual values as determined by the NOVA Stat Profile-1 and by flame photometry are shown in Table 5. The mean potassium concentration as determined by the NOVA instrument was 4.31 mmoles/l, while that determined by flame photometry was 4.46 mmoles/l. There was no statistically difference between these two means. Figure 5 shows that for potassium concentration, the regression of Y on X again exhibited an extremely high regression coefficient, and was extremely similar to the theoretical value of 1. For potassium, there was no significant difference between the slope of the experimentally determined regression and the theoretical line of identity.

Figure 6 shows results obtained in the total number of blood samples for sodium ion concentration and Table 6 shows the individual values determined by the NOVA Stat Profile-1 and by flame photometry. The mean value for sodium concentration as determined by the NOVA instrument was 142.4 mmoles/l, and that determined by flame photometry was 139.8 mmoles/l. There was no significant difference between these two means. From analyses of Figure 6 it is apparent that the regression of Y (ion selective electrode) on X (flame photometry) exhibited more "spread" about the regression line than in previous examples. This is illustrated by the fact that the linear regression coefficient, while moderately high, was less than in previous examples. However, when analyzing the data as illustrated in Figure 6, it must be considered that the values for sodium ion concentration did not vary greatly among the blood samples analyzed. Such absence of a wide variation would naturally cause the regression of Y on X to be small. For this reason, in the case of sodium concentration, it is probably more important to look at the difference between the means as determined by the two techniques

than to consider the linear regression. When considering the difference in the two means, it is evident that the Stat Profile-1 did not provide results which were significantly different from those provided by flame photometry.

Figure 7 shows the results obtained by calcium ion concentration among the total number of blood samples obtained. Table 7 shows the individual values obtained using the NOVA Stat Profile-1 and the standard colorometric technique. In the case of calcium, it should be recalled that the colorometric technique provide values for total serum calcium, including ionized calcium and bound calcium, while ions selective electrode technology such as employed by the NOVA instrument provides values only for ionized calcium. With this in mind, it can be predicted that the values obtained by the NOVA instrument would be very near to 50% of those obtained by the colorometric technique. An examination of the means shows that the mean value as determined by the NOVA was 1.27 mmoles/l while that obtained by the colorometric technique was 2.41 mmoles/l. In other words, the NOVA values were approximately 52% of those determined by the colorometric technique. An examination of Figure 7 shows that the regression of Y on X exhibited only a moderately high regression coefficient, indicating a moderate spread of the values about the calculated regression line. As in the case of sodium, it is felt that this moderate spread about the regression line is partially due to the absence of a high variation in calcium ion concentration among the blood samples analyzed. It is also felt that this spread about the linear regression line is partially due to the fact that there is some variation in the percentage of serum calcium that is in the ionized form from individual to individual. Thus, the data indicating the validity of using ion selective electrodes for calcium ion determination is less conclusive than that for other data variables. However, based on the examination of mean values and on the established knowledge that approximately 50% of serum calcium is in the ionized form, it is felt that the data provide a reasonable indication that ion selective electrode technology as employed by the NOVA Stat Profile-1 provides a valid technique for calcium determination.

Figure 8 shows data obtained for blood hemoglobin (Hbc) concentration in the total number of human blood samples analyzed. Table 8 shows the individual values obtained using the NOVA instrument and the Radiometer OSM-2 hemoximeter. Recall that the NOVA instrument calculates hemoglobin concentration from the measured value for hematocrit, while the OSM-2 directly measures hemoglobin concentration. The mean hemoglobin concentration as calculated by the NOVA instrument was 12.4 grams/100 ml blood, while that measured by the hemoximeter was 11.3 grams/100 ml blood. There was no statistically significant difference bewteen these 2 means. Furthermore, Figure 8 shows that the linear regression of Y on X exhibited a high regression coefficient and was very close to the theoretical line of identity. There was no significant difference between the slope of the experimentally determined regression line and the line of

identity.

Figure 9 shows the results obtained in the total number of human blood samples for oxygen saturation (O2SAT). Table 9 shows individual values for oxygen saturation as determined by the NOVA and by the hemoximeter. The NOVA instrument calculates oxygen saturation from measured values of PO_2, while the hemoximeter directly measures oxygen saturation. Note that both the NOVA and hemoximeter gave mean values of oxygen saturation of 80.4%. These means were not statistically different. Also note in Figure 9 that the linear regression of Y on X showed an extremely high regression coefficient and was very close to the theoretical line of identity. There was no significant difference between the slope of the regression experimentally determined and the theoretical slope of 1.

Figure 10 shows values determined in the total number of human blood samples for oxygen content (O2CT). Table 10 shows individual values determined by the NOVA instrument and calculated from the values of hemoglobin and hemoglobin saturation as measured directly with the Radiometer hemoximeter. The mean value calculated by the NOVA instrument was 13.2 ml/100 ml blood, while that obtained from the hemoximeter was 11.9 ml/100 ml blood. There was no statistically significant difference between these means. Furthermore, it can be seen in Figure 10 that the linear regression of Y on X exhibited a high regression coefficient and was very similar to the theoretical line of identity. There was no significant difference between the slope of the experimentally determined regression line and the theoretical line.

Figure 11 shows the data obtained in the total number of blood samples for bicarbonate (HCO3) concentration in blood. Table 11 shows the individual values as calculated by the NOVA instrument and as calculated by the Corning blood gas machine. The mean value calculated by the NOVA was 22.9 mmoles/liter, while that calculated by the Corning instrument was 21.8 mmoles/liter. There was no significant difference between these means. The linear regression of Y on X showed a high regression coefficient, and the slope of this experimentally determined regression was not different from the theoretical slope of 1.

(2) Selective Analyses of Human Blood from Dialysis Unit. Fifty blood samples were acquired from the Renal Dialysis Unit; 25 of these samples were from patients immediately prior to dialysis while 25 were from those same patients immediately following dialysis. Since the blood obtained from these patients provided values for data variables which were, in many cases, far different from values in normal human subjects, analysis of these samples provided an opportunity to assess the validity of the NOVA Stat Profile-1 in the quantitation of abnormal values for data variabls. In addition, comparison of predialysis versus postdialysis data provided some insight into possible interference of large changes in one data variable on the ability of the Stat Profile-1 to quantitate accurately other data

variables. Some of the major features which become evident upon analysis of the dialysis data are as follows:

Table 12 shows all values for PO_2 determined with the NOVA instrument and with Corning instrument both before dialysis and after dialysis. The means $\pm$ standard errors are also illustrated. Blood from these patients was acquired from an arterial shunt, and the values for blood PO_2 are, therefore, high. Mean PO_2 prior to dialysis was 111.1 mmHg with the NOVA instrument compared to 112.9 mmHg with the Corning instrument. There was no significant difference in these 2 means. After dialysis, mean PO_2 with the NOVA instrument was 105.0 mmHg compared to 102.0 mmHg with the Corning instrument. These 2 means were also not significantly different. Despite the fact that blood was well oxygenated in these patients, the oxygen-carrying capacity of blood was lower than normal due to a reduced hematocrit. A reduced hematocrit in patients with renal disease is expected because of the diminished formation of the hormone erythropoetin normally formed by the healthy kidney. The mean hematocrits observed in the dialysis patients is shown in Table 13. Note that before dialysis, the hematocrit as determined by the NOVA instrument was 31.4%, while that determined by the centrifugation technique was 28.8%. There was no significant difference between these 2 means. After dialysis, the hematocrit showed an increase using both methods of determination. Thus with the NOVA instrument, the post dialysis hematocrit was 34.0%, while that by the centrifugation technique was 31.4%. There was no significant difference between these 2 means. It is noteworthy that both methods of analysis showed a similar increase in hematocrit when comparing the predialysis to the post dialysis values. This increase in hematocrit is likely due to hemoconcentration caused by a reduction in blood volume after dialysis. Thus, these data demonstrate the value of hematocrit measurements in providing a ready assessment of changes in blood volume. Associated with the reduced hematocrit seen in patients with renal disease, the hemoglobin concentration of blood was also reduced as shown in Table 14. Before dialysis, the hemoglobin concentration as determined by the NOVA was 10.5 grams/100 ml, while that determined by the hemoximeter was 8.6 grams/100 ml. There was no significant difference in these 2 means. Furthermore, associated with the increase in hematocrit after dialysis, there was an increase in hemoglobin concentration after dialysis as determined by both methods. Thus, after dialysis the hemoglobin concentration as determined by the NOVA instrument was 11.3 grams/100 ml, while that determined by the hemoximeter was 9.5 grams/100 ml. There was no significant in these postdialysis means. Even though the oxygen carrying capacity of blood in renal dialysis patients was low, the available hemoglobin was well saturated as indicated in Table 15. Note that both before and after dialysis the oxygen saturation of blood was nearly 100% as determined by both instruments. There was no significant difference in the saturation means between the 2 instruments either before or after dialysis. Although the PO_2

was high in the dialysis patients, and even though hemoglobin was nearly 100% saturated in these patients, the low concentration of hemoglobin in the renal disease patients resulted in a reduced oxygen content of blood as shown in Table 16. Note that before dialysis the oxygen concentration as determined by the NOVA was 14.1 ml/100 ml, while that determined by the hemoximeter was 12.2 ml/100 ml. After dialysis the oxygen content as determined by the NOVA was 15.3 ml/100 ml, while that determined by the hemoximeter was 13.1 ml/100 ml. There was no significant difference in either of the means as determined by the 2 techniques.

The major ion concentration abnormality noted in the dialysis patients was with potassium ion. Table 17 shows values for potassium ion concentration before and after dialysis as determined with ion-selective electrode technology using the NOVA and by flame photometry. Note that the potassium ion concentration prior to dialysis was 5.11 mmoles/liter as determined by the NOVA and 5.31 mmoles/liter as determined by flame photometry. There was no significant difference in these means. After dialysis, the potassium concentration was substantially reduced. Thus, after dialysis, the potassium concentration was 3.51 as determined with the NOVA and 3.66 as determined with flame photometry. There was no significant difference in the postdialysis means, although both the NOVA and flame photometry showed a significant reduction in potassium in the postdialysis samples compared to the predialysis samples. Even though potassium was significantly reduced after dialysis, this reduction in potassium did not affect the accuracy of the NOVA in determination of sodium concentration. Table 18 shows values for sodium concentration determined by the NOVA and by flame photometry both before and after dialysis. A comparison of the means both before and after dialysis showed no significant difference between the 2 techniques. Table 19 shows values for calcium concentration determined by the NOVA and by a standard colorometric technique both before and after dialysis. Note that prior to dialysis, the ionized calcium concentration as determined by the NOVA instrument was 52% of the total calcium as determined by the colorometric technique. Following dialysis, calcium concentration showed a slight increase as measured by both techniques. However, the ionized calcium concentration as determined by the NOVA was still 51% of that determined by the colorometric technique. Finally, Table 20 shows values for pH before and after dialysis as determined by the NOVA instrument and as determined by the Corning Blood Gas Analyzer. Prior to dialysis, the pH as determined by the NOVA was 7.310 and that determined by the Corning was 7.323. There was no significant difference between these 2 means. After dialysis, the pH increased and showed a value of 7.353 by the NOVA instrument and 7.355 by the Corning instrument. There was no significant difference in these postdialysis means.

(3) Analysis of Normal Human Blood. Table 21 shows values obtained from 14 normal human volunteers as measured with the NOVA Stat Profile-1 and the respective Gold Standard technique. It may be noted, that with the exception of calcium concentration, there was no significant difference in the means for any data variable as determined by the 2 techniques ($P < 0.05$). As expected, the mean calcium ion concentration showed a significant difference due to the fact that ion-selective electrode technology measures ionized calcium concentration only, while the standard colorometric technique measures total calcium, including ionized and bound calcium.

(4) Studies on Canine Blood. Fifty-six samples of canine blood were analyzed. These values were compared to values obtained by standard techniques with the exception of the blood concentration of the ions potassium, sodium, and calcium. Concentrations for these ions were not determined by flame photometry or colorimetry. Regression analyses performed for all other data variables, comparing the results of the NOVA Stat Profile-1 to standard techniques, yielded results similar to those obtained in human blood samples. Thus, for PO_2, PCO_2, pH, hematocrit, hemoglobin concentration, hemoglobin saturation, oxygen concentration, and bicarbonate concentration, the slope of the regressions of the NOVA values on the standard values was not statistically different from unity. Although the values for blood electrolytes were not compared to a standard technique, the mean values obtained were similar to those for human blood. Thus, the concentrations for sodium, potassium and calcium ions were 150.2, 3.16, and 1.25 mmoles/liter, respectively.

Interesting results were observed in individual experiments on dogs. Figure 12 shows changes in values for blood gases and pH in a single animal when ventilation rate was at a normal value of 12/minute, when it was increased to 18/minute for 5 minutes and when it was returned to 12/minute for 5 minutes. Note that during hyperventilation arterial blood PO_2 blood exhibited a definitive increase while arterial and venous PCO_2 exhibited a definitive reduction. Arterial and venous pH also showed detectable increases, indicating that the blood became more alkalotic. These results are those expected with hyperventilation. After 5 min of recovery, it can also be noted in Figure 12 that blood gas and pH values tended to return toward the control values. Figure 13 shows values for arterial and venous electrolyte concentrations during hyperventilation and recovery. It can be seen that there were no substantial changes in the value of any electrolyte. The results shown in Figures 12 and 13 typify those seen in 4 experiments examining the effects of hyperventilation.

Figure 14 shows changes in arterial and venous blood gases and pH as measured with the NOVA instrument during hypoventilation. In this case ventilation rate was reduced from a control value of 12/minute to 6/minute for 5 minutes and was returned to 12/minute for 5 minutes before blood samples were

withdrawn. Note that during hypoventilation, both arterial and venous PO_2 showed substantial reductions, while arterial and venous PCO_2 showed substantial increases. Arterial and venous blood pH tended to decrease. These changes are those which would be expected during impaired oxygenation of arterial blood secondary hypoventilation. Note that during the recovery period, the blood gas and pH values tended to return to the control. Figure 15 shows the blood electrolyte changes during hypoventilation in this same animal. Again, it may be noted that there were no substantial changes in any blood electrolyte value. The results shown in Figures 14 and 15 typify those seen in 5 experiments.

Figure 16 shows blood gas and pH values determined in a representative animal during hypovolemia. In this case blood was withdrawn from an animal until mean arterial blood pressure fell to a value of 40 mmHg. The hemorrhage values shown in Figure 16 are from blood withdrawn 30 minutes after producing hypovolemic hypotension. Note that following hemorrhage, arterial PO_2 showed a substantial increase while venous PO_2 decreased drastically. The increase in arterial PO_2 was likely due to increased oxygenation of arterial blood caused by hyperventilation. Thus, the increase in venous POC_2 along with a reduction in pH are known to stimulate the respiratory center of the brainstem. The reduction in venous PO_2 is likely due to the impaired perfusion of peripheral tissues. This impaired perfusion reduces oxygen transport to peripheral tissues causing them to increase oxygen extraction from the arterial blood as it perfuses the tissues. Consequently, the venous blood shows an abnormally low PO_2. Note also that arterial PCO_2 showed a drastic reduction while venous PO_2 showed a drastic increase following hemorrhage. Again, the reduction in PCO_2 in arterial blood reflects a hyperventilation while the increase in venous PCO_2 reflects the low perfusion of peripheral tissues. The reduced pH in arterial and venous blood, as pointed out in section IIA above, reflects the fact that with the low perfusion of peripheral tissues, these tissues begin to metabolize anaerobically. Figure 17 shows blood electrolyte changes during hypovolemia in this same animal. The most notable feature is that neither sodium nor calcium showed substantial increases in concentration, but arterial and venous potassium levels showed drastic increases. As pointed out in Section IIA above, these increases in blood potassium level most likely reflect an oxygen-deficiency induced failure of peripheral tissue membrane mechanisms for maintaining extracellular fluid potassium level low while maintaining intracellular potassium levels high.

In 6 dogs, large arterial blood samples were obtained, and aliquots of these large samples were analyzed by the NOVA Stat Profile-1 4 times consecutively. Table 22 shows the results of these analyses. Note that in each of the 6 blood samples, there was good agreement in the values for all data variables during the 4 consecutive analyses. Thus, of the 66 mean values shown in Table 22, there were only 5 cases in which a determined value deviated from the mean by more than 5%. One such case was for

hematocrit, 2 cases were for calcium, 1 case was for hemoglobin concentration, and 1 case was for oxygen concentration. Thus, these results indicate an acceptable level of consistency in data variable determination by the NOVA Stat Profile-1.

B. Experience with Performance and Maintenance of Prototype.

In general, it can be stated that the operation and maintenance of the NOVA Stat Profile-1 is relatively simple and trouble-free. One member of our investigative team, Student Doctor John R. Randall, took a 2-day course on operation of the instrument offered by NOVA Biomedical Company. Upon completion of this course, it was found to be relatively simple to instruct other technicians and personnel in the maintenance and operation of the instrument. Without doubt, the instrument is much more simple to operate and maintain than other blood gas instrumentation or other instruments used in our laboratories for blood chemistry analysis. Step-by-step and easy-to-follow instructions for operation and maintenance of the Stat Profile-1 instrument are presented in the user's manual accompanying the instrument (see Appendix). A summary of maintenance procedures which were experienced in our use of the instrument is as follows:

The reagent pack is stated to contain enough reagent for analysis of 300 samples. In our experience, this is an accurate estimate. During the course of 4 months of use of the instrument in its evaluation, the reagent pack was changed only one time. During this time, over 300 samples, including those relevant to the current work, were analyzed. There was no apparent problem with deterioration or contamination of the reagents during this period, and the results provided by the instrument proved to be reliable and accurate throughout the use of one reagent pack.

The instrument contains a Waste-Reagent Harness which consists of a system of tubing for the reagents and the disposed waste. This harness required changing one time during the course of our use of the instrument. The changing procedure is a simple one and is facilitated by the design of the instrument.

The PO_2 and PCO_2 electrodes contain membranes at the electrode tips which require periodic replacement. As part of the routine maintenance, each of these membranes was changed 3 times during our use of the instrument. The membrane replacement kits provided with the instrument make the replacement procedure a simple one even for the untrained technician. After replacement, the membranes require "conditioning" with whole blood before use of the instrument. The entire procedure normally requires approximately 30 minutes.

The ion-selective electrodes for sodium, potassium, and calcium have a finite life span. During the course of our use of the instrument, the calcium electrode required replacing twice, and the potassium electrode required replacing once. Replacement of these electrodes is a simple "snap-out, snap-in" procedure which requires only a few minutes and can be performed with only

minimal training. The design of the instrument is such that all electrodes are located in an easily accessible compartment on the front face of the instrument.

Overall operation of the NOVA Stat Profile-1 is extremely simple and is facilitated by user-friendly instructions displayed on a CRT screen. The information displayed on this screen not only provides user instructions but also alerts the user of errors in the system. Loading of the electrode compartment with sample fluid is facilitated by an inlet port on the front face of the instrument. Fluid is actively pulled through this inlet port. In our experience, blood was withdrawn from the vacutainer to a syringe and loaded through the inlet port from the syringe. Only very rarely did this procedure cause air bubbles to be loaded into the electrode compartment. In these few cases, the CRT alerted the user. Although not employed in our experience, capillary blood (finger puncture) may be sampled with a capillary tube, and the blood loaded into the instrument from the capillary tube. This procedure requires a capillary tube adapter which fits the tube to the inlet port of the instrument.

In summary, operation and routine maintenance procedures on the NOVA Stat Profile-1 are extremely simple and can be accomplished with a minimal training.

C. FIGURES

FIGURE 1.

PO_2 in all human samples: NOVA vs Standard. Units = mmHg.

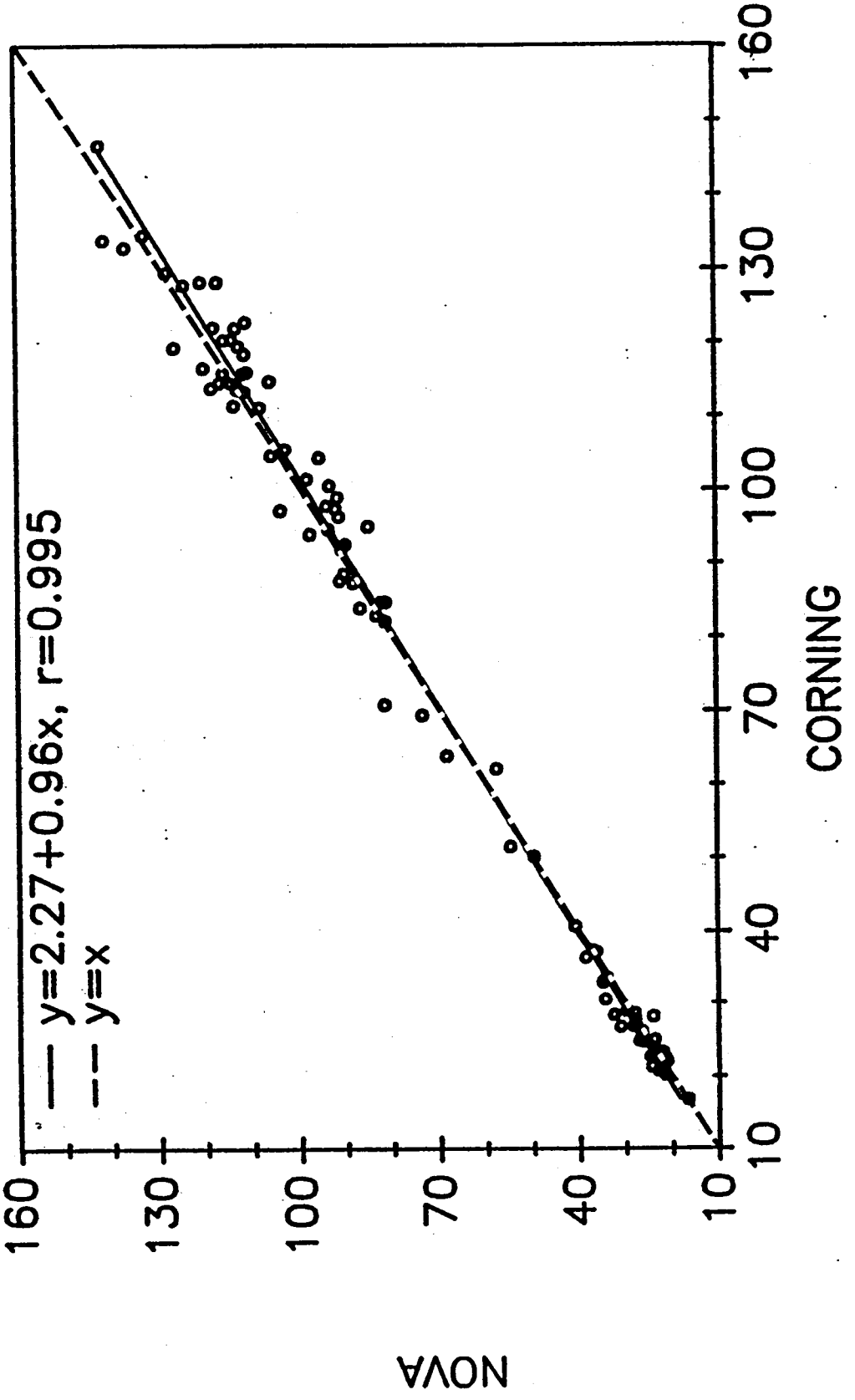


FIGURE 2.

PCO_2 in all human samples: NOVA vs Standard. Units = mmHg.

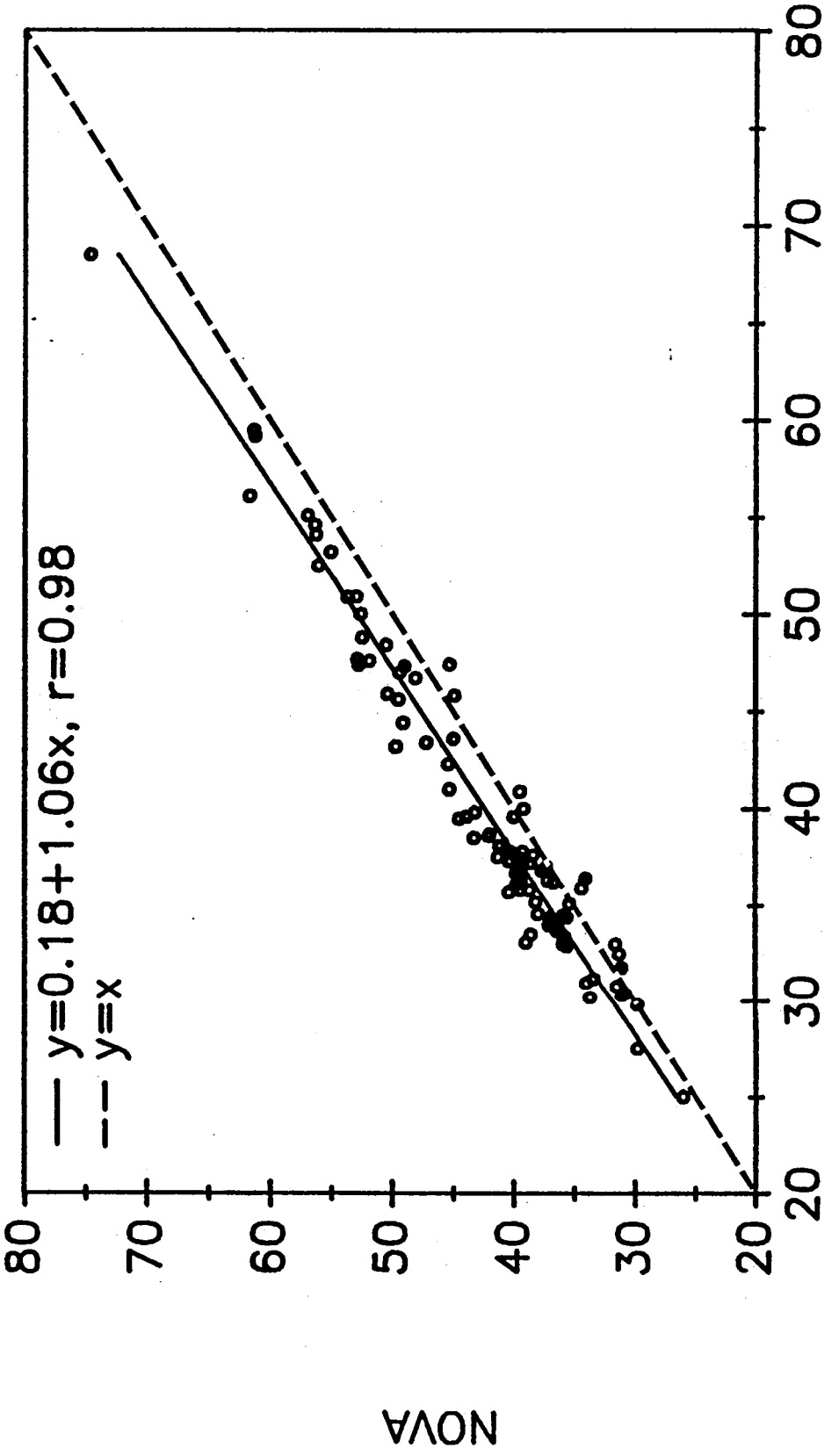


FIGURE 3.

pH in all human samples: NOVA vs Standard. Units = pH units.

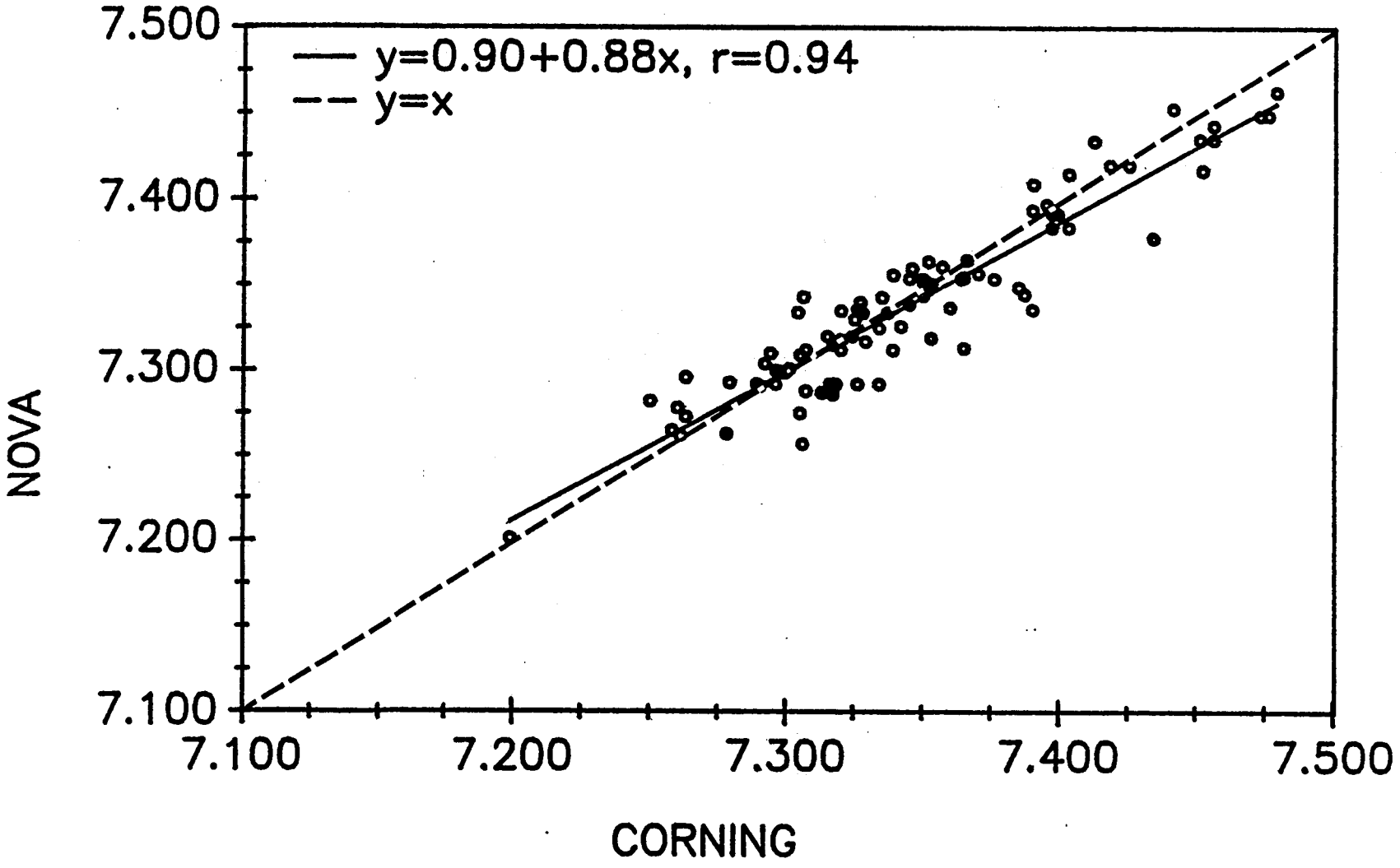


FIGURE 4.

Hematocrit in all human samples:
NOVA vs Standard. Units = %
blood volume.

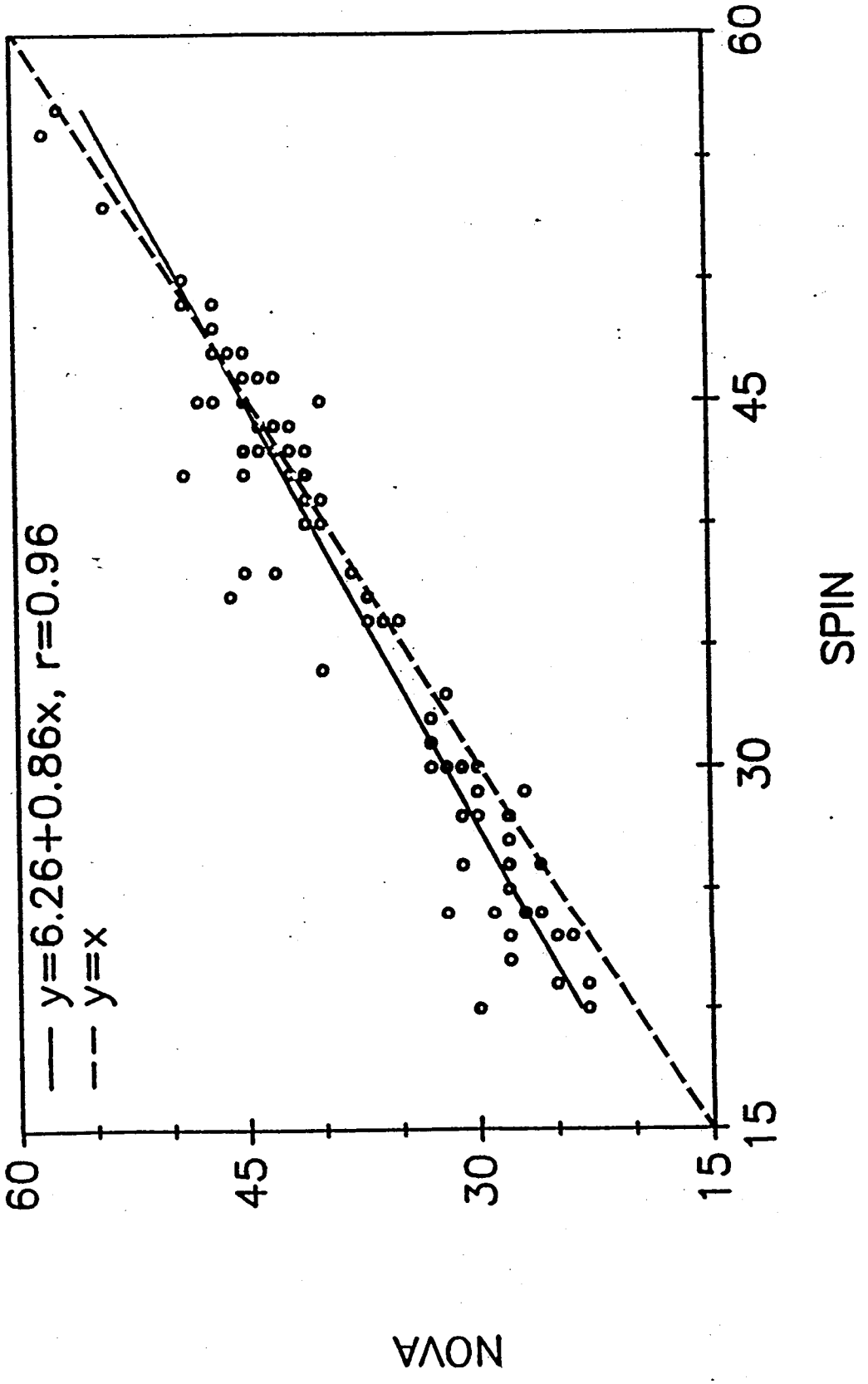


FIGURE 5.

Potassium in all human samples:
NOVA vs Standard. Units - mmoles/
liter.

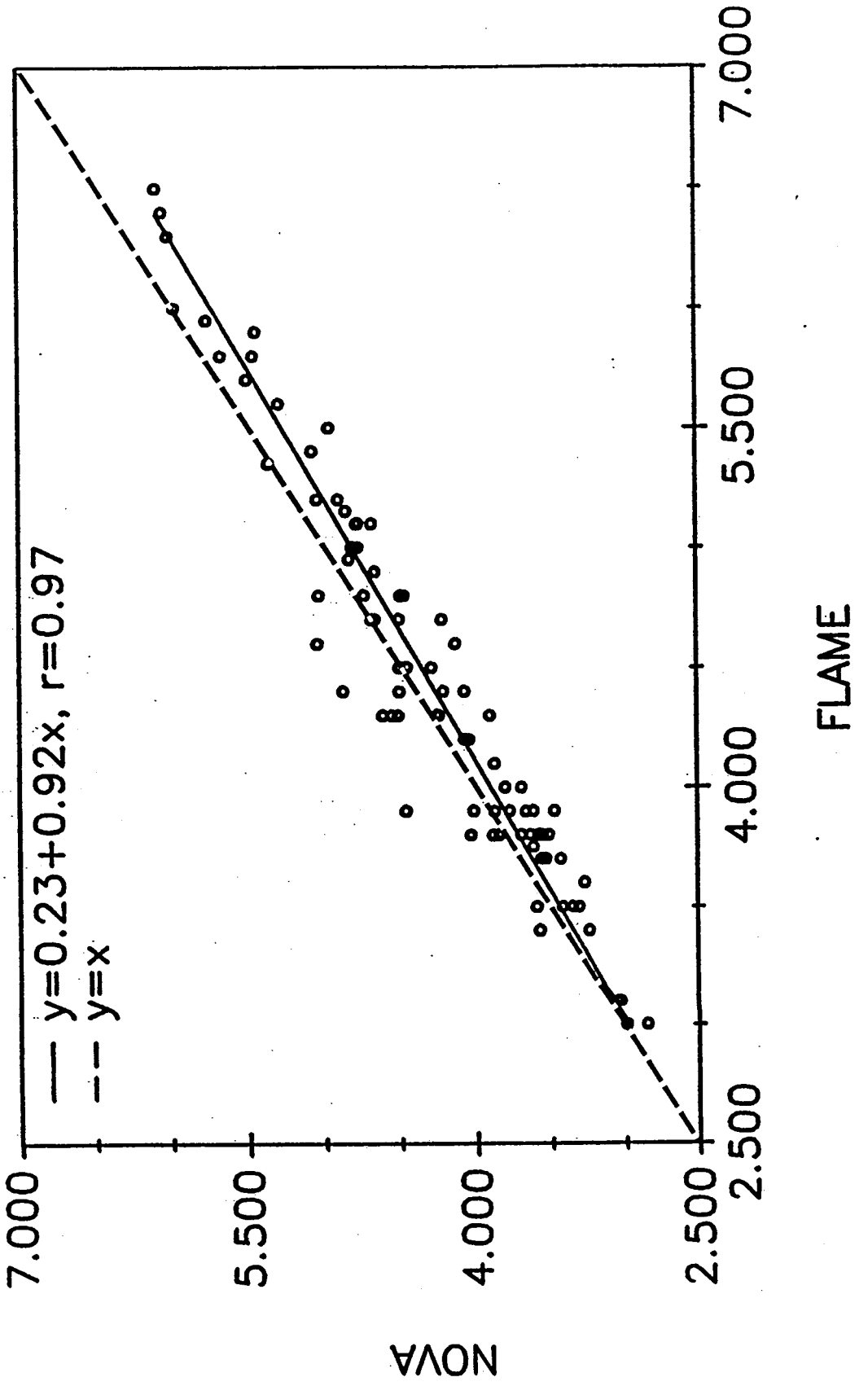


FIGURE 6.

Sodium in all human samples: NOVA vs Standard. Units = mmoles/liter.

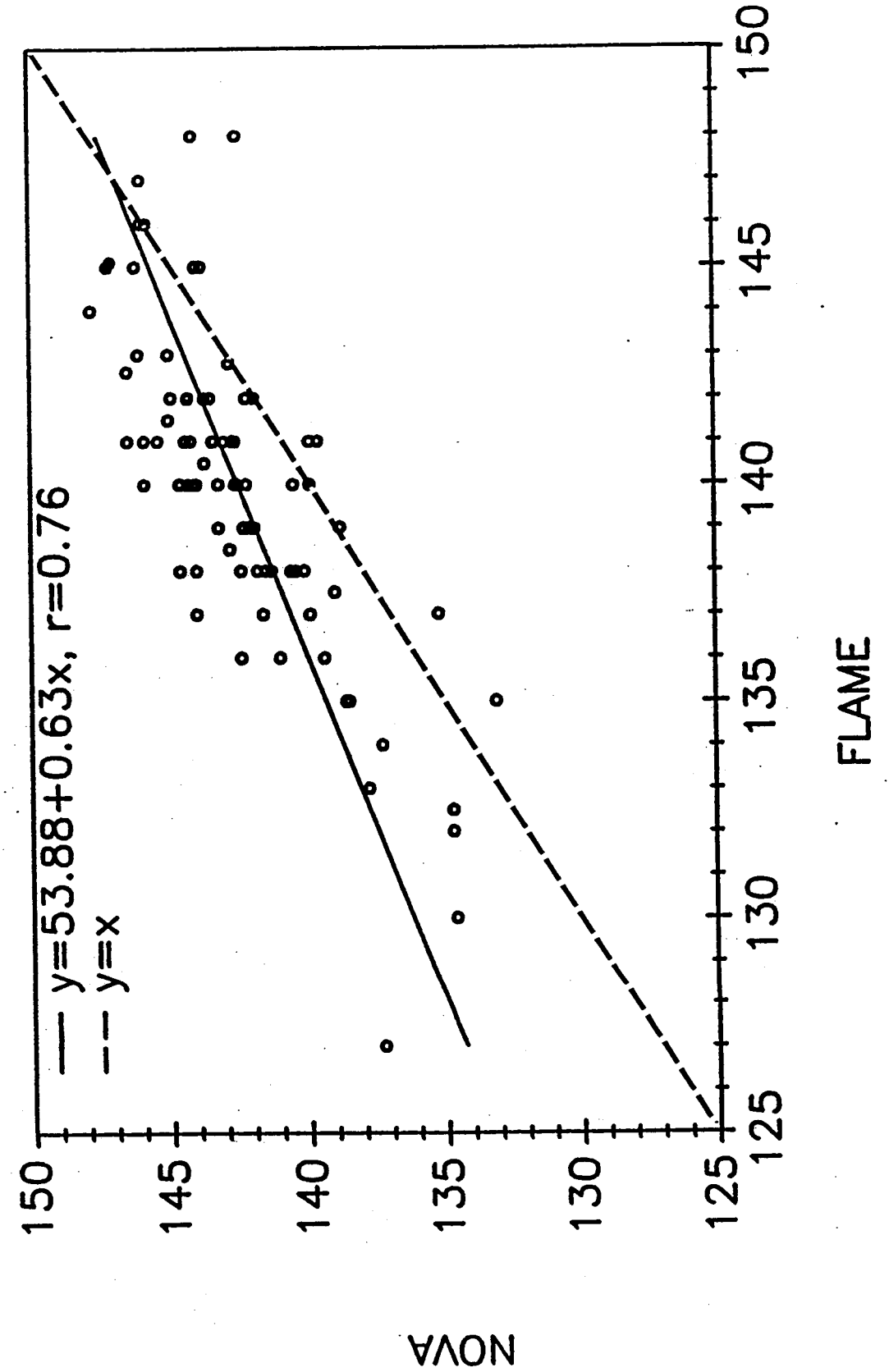


FIGURE 7.

Calcium in all human samples: NOVA vs Standard. Units = mmoles/liter.

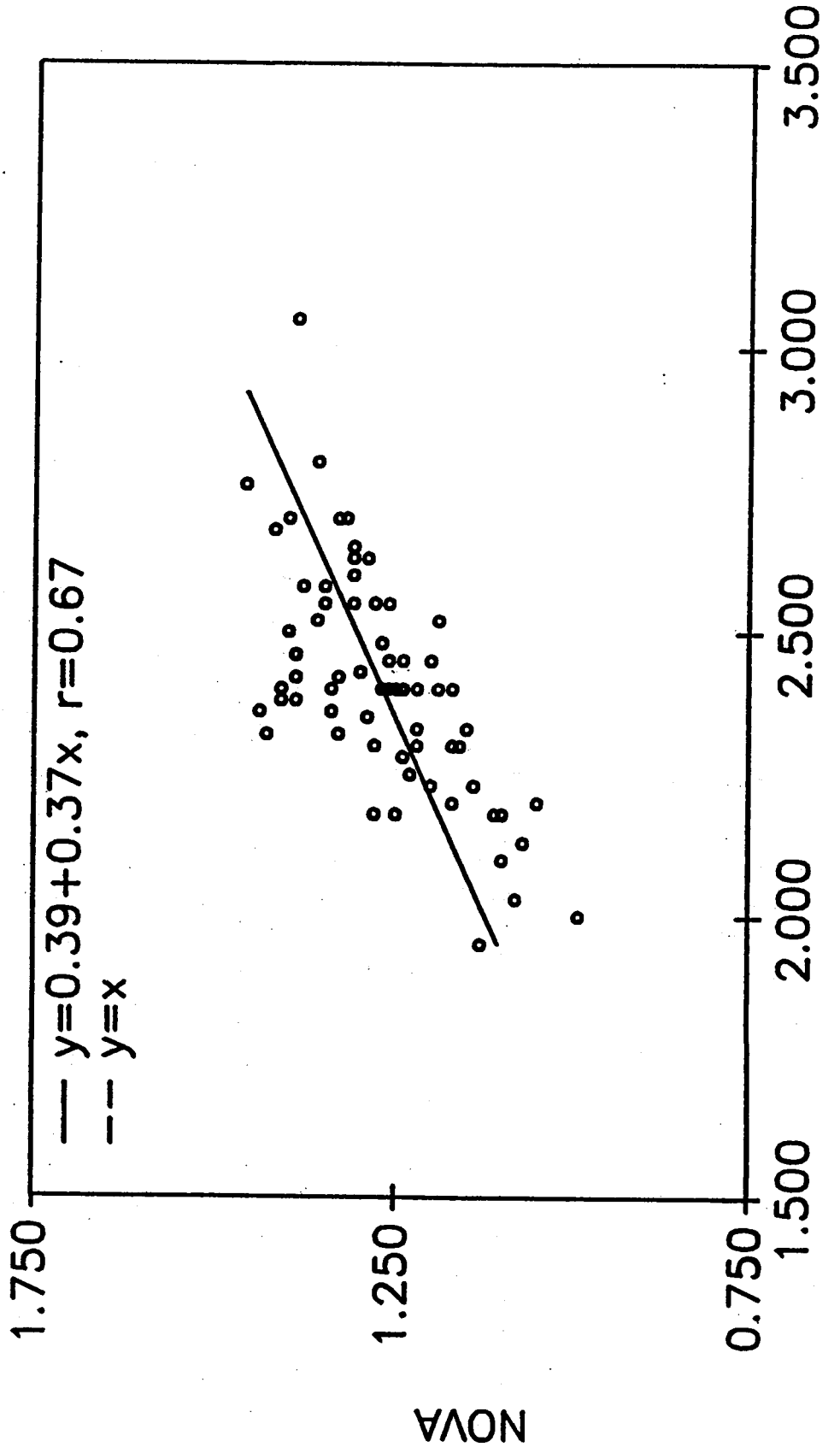


FIGURE 8.

Hemoglobin in all human samples:
NOVA vs Standard. Units = grams/
100 ml blood.

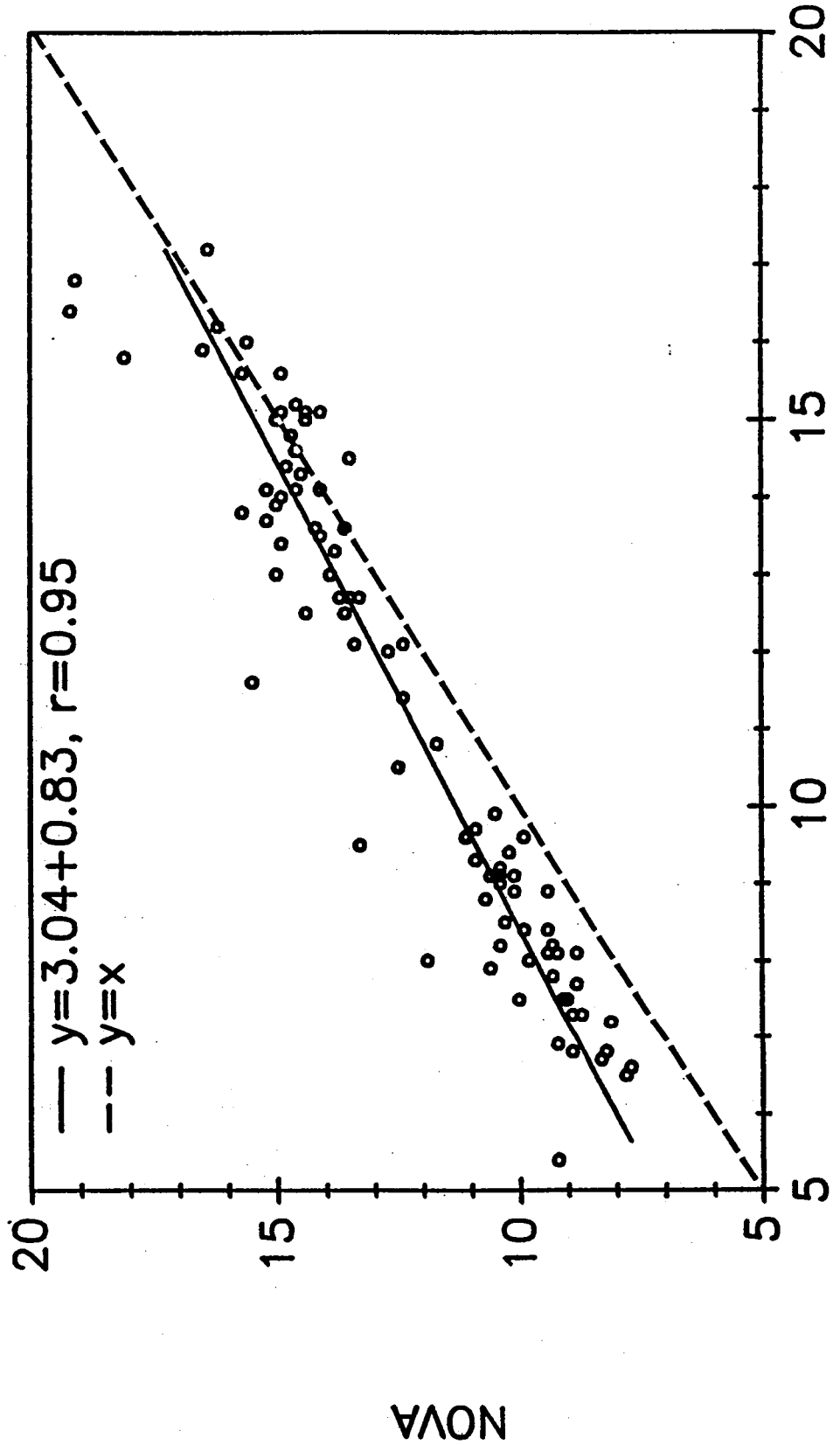


FIGURE 9.

Oxygen saturation in all human samples. NOVA vs Standard. Units = %

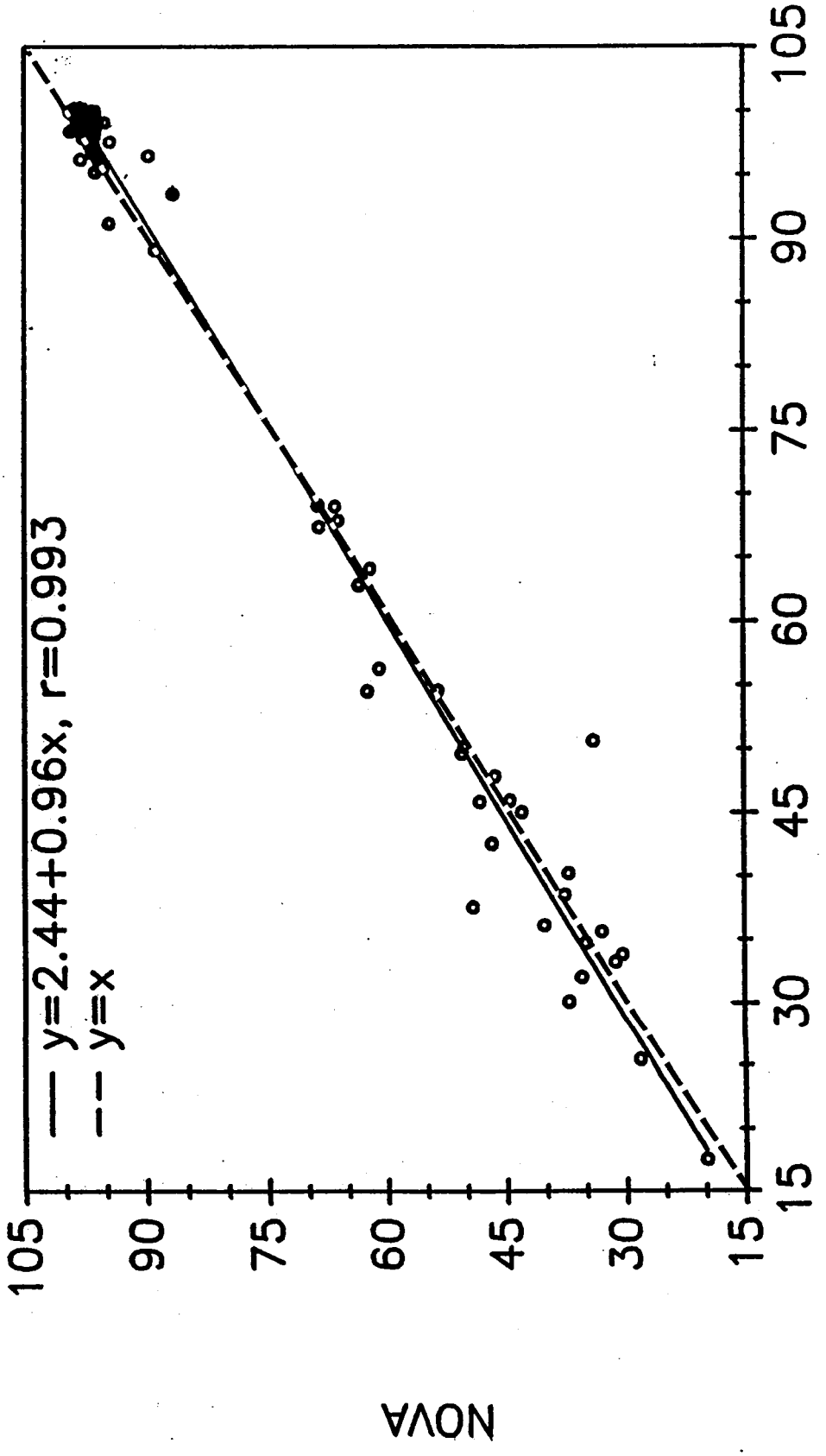


FIGURE 10.

Oxygen content in all human samples:
NOVA vs Standard. Units = ml/100 ml
blood.

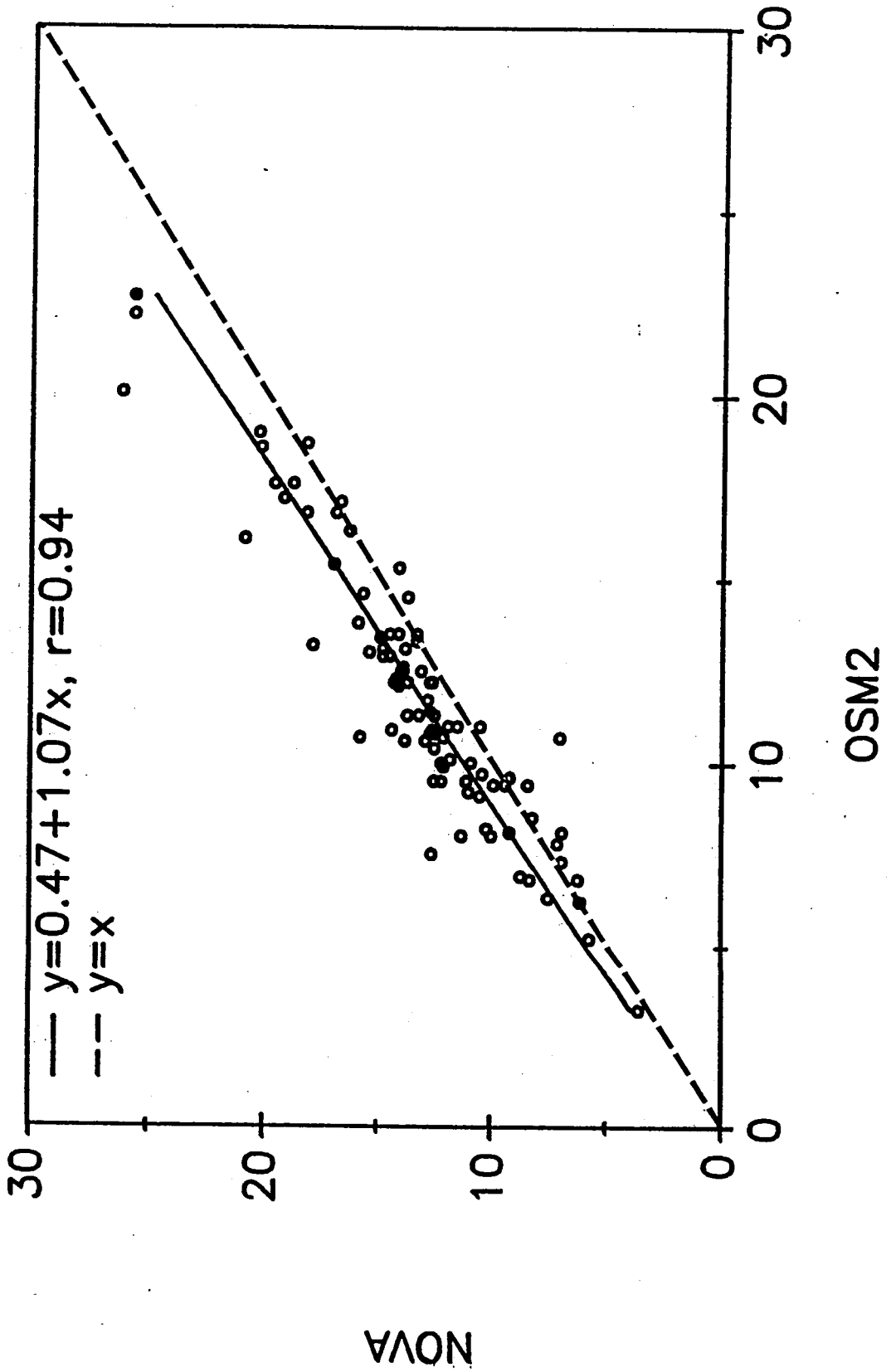


FIGURE 11.

Bicarbonate in all human samples: NOVA vs Standard. Units = mmoles/liter.

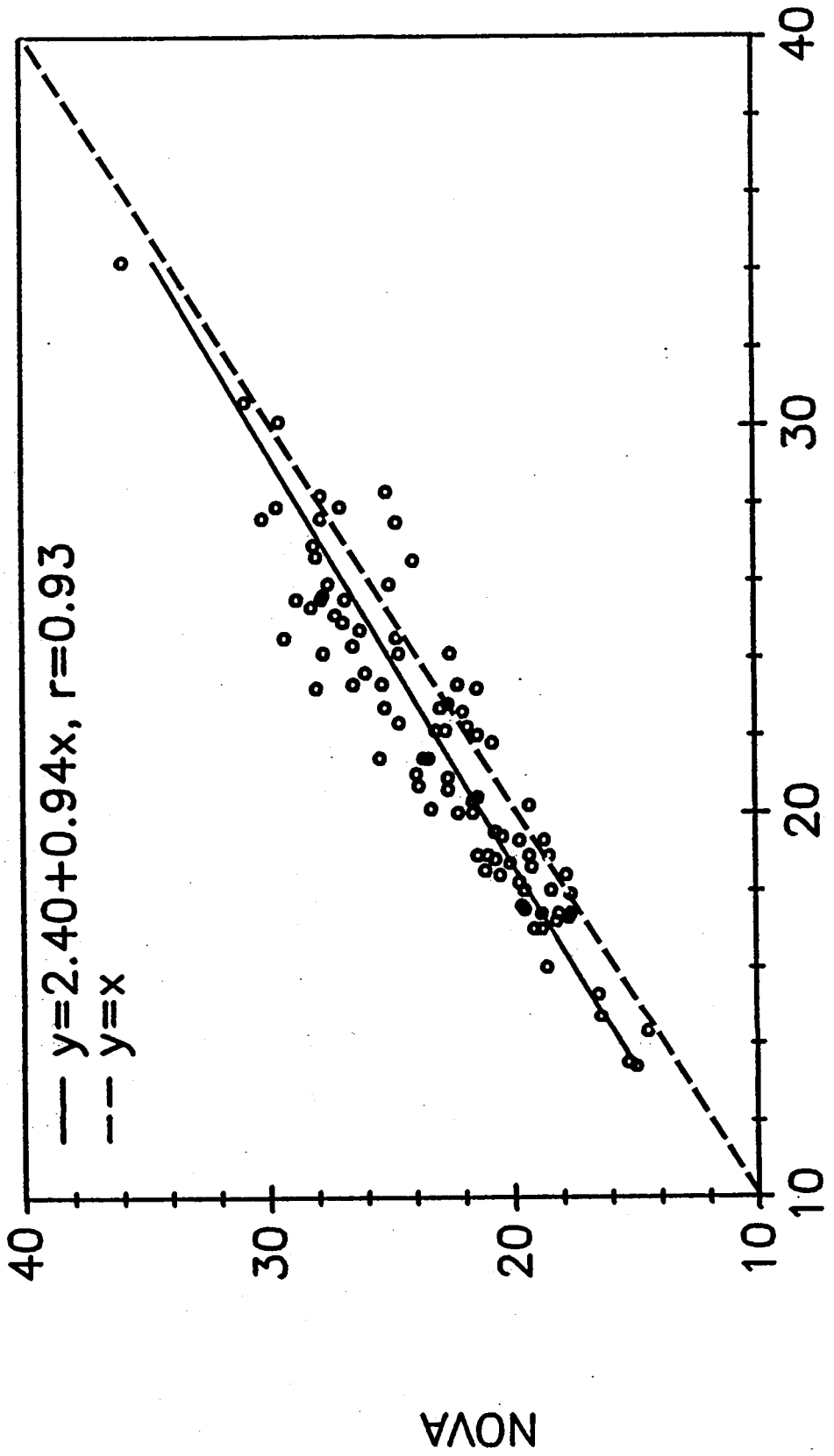


FIGURE 12

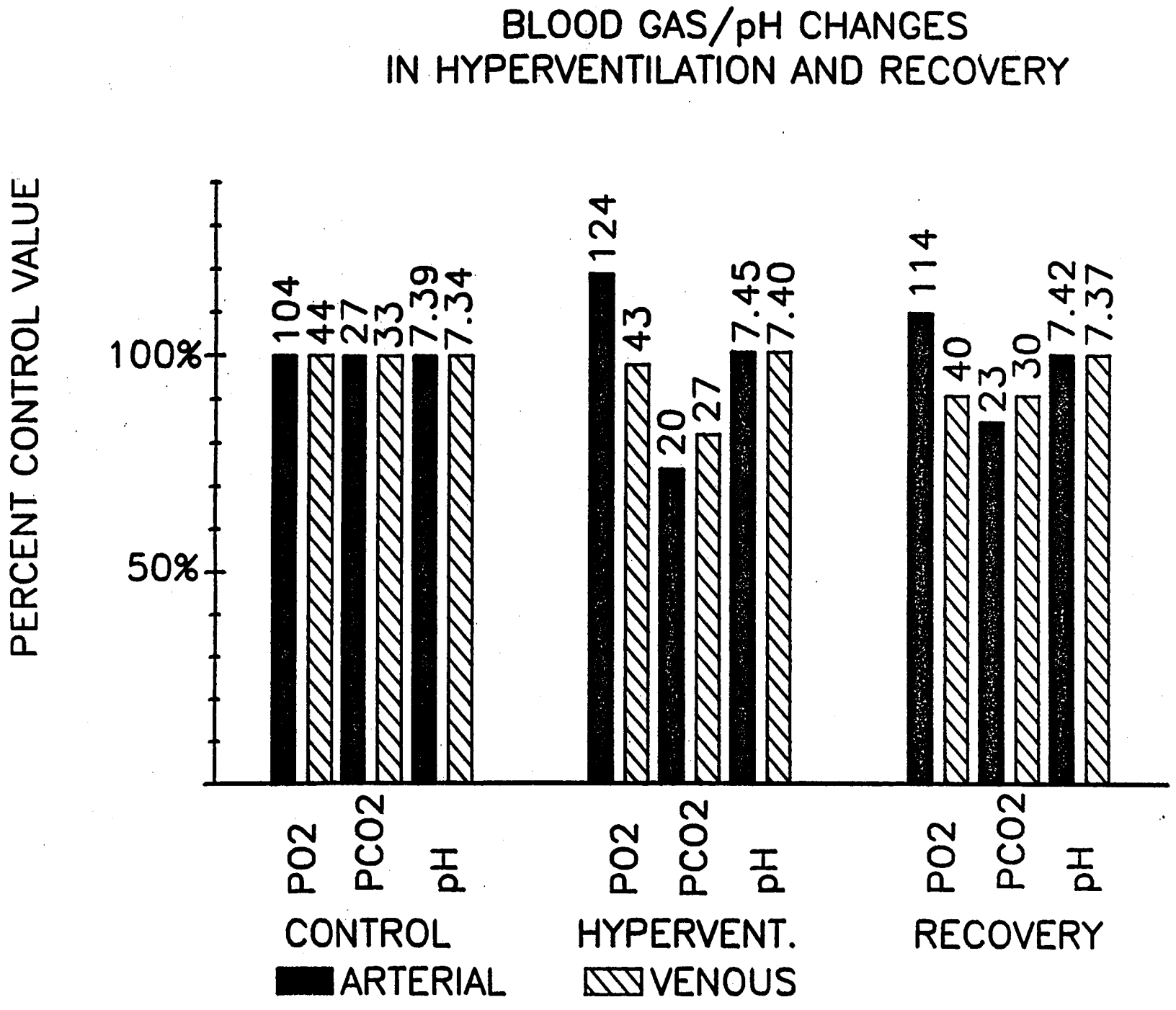

BLOOD GAS/pH CHANGES
IN HYPERVENTILATION AND RECOVERY
PERCENT CONTROL VALUE
100%
50%
104
44
27
33
7.39
7.34
124
43
20
27
7.45
7.40
114
40
23
30
7.42
7.37
PO2
PCO2
pH
PO2
PCO2
pH
PO2
PCO2
pH
CONTROL
HYPERVENT.
RECOVERY
ARTERIAL
VENOUS

FIGURE 13

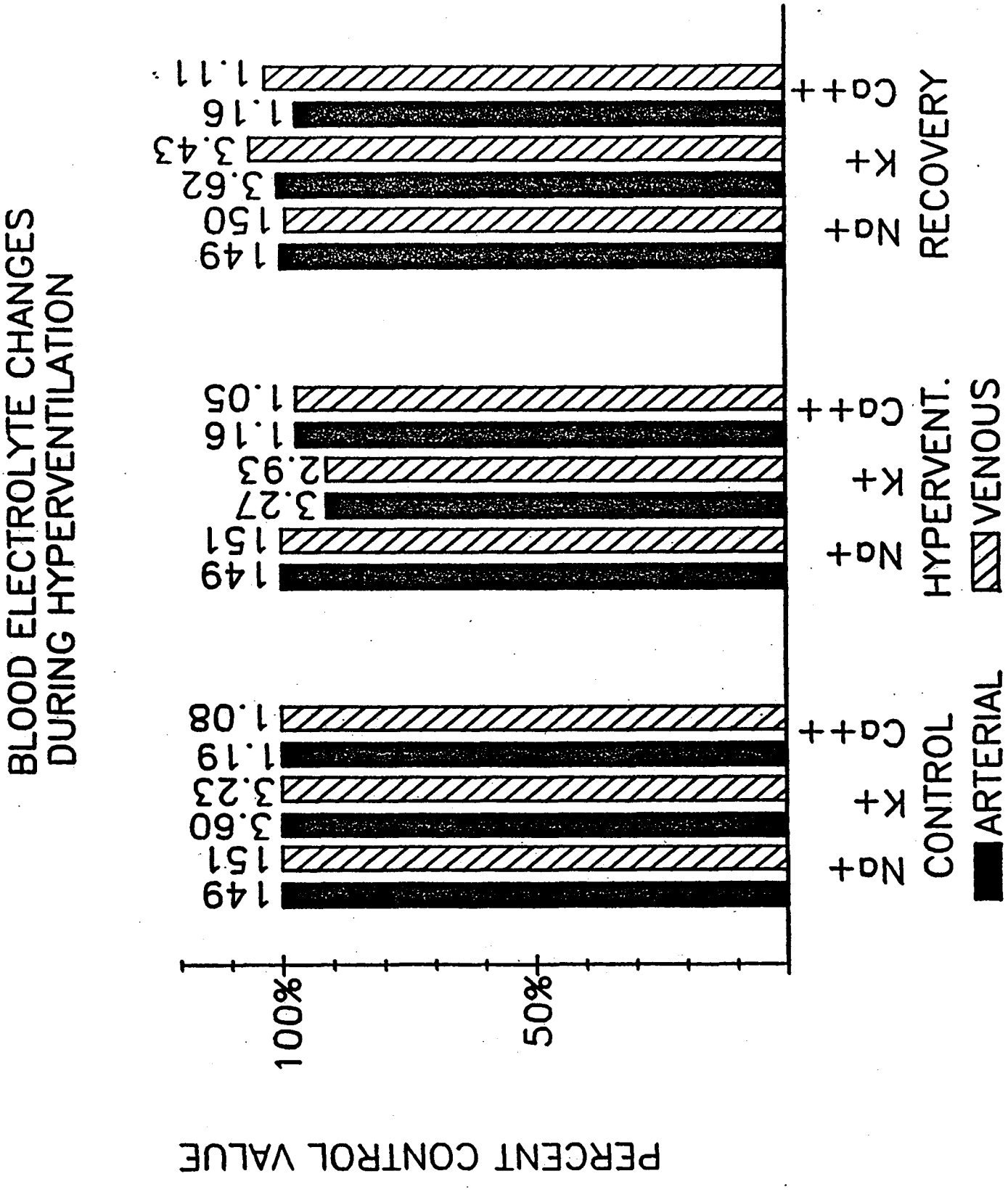

BLOOD ELECTROLYTE CHANGES
DURING HYPERVENTILATION
PERCENT CONTROL VALUE
100%
50%
CONTROL
HYPERVENT.
RECOVERY
ARTERIAL
VENOUS
Na+
K+
Ca++
149
151
3.60
3.23
1.19
1.08
149
151
3.27
2.93
1.16
1.05
149
150
3.62
3.43
1.16
1.11

FIGURE 14

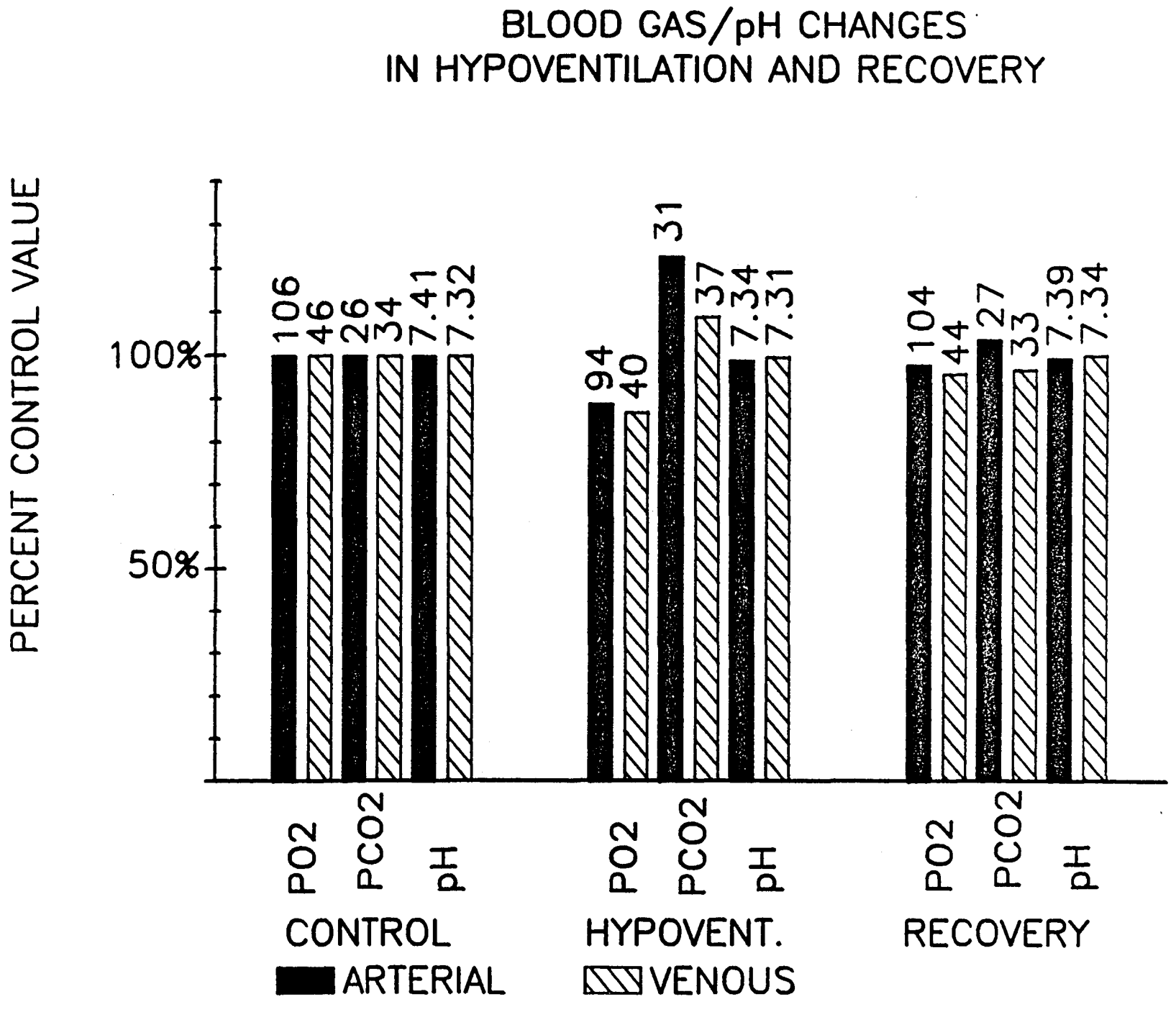

BLOOD GAS/pH CHANGES
IN HYPOVENTILATION AND RECOVERY
PERCENT CONTROL VALUE
100%
50%
106
46
26
34
7.41
7.32
94
40
31
37
7.34
7.31
104
44
27
33
7.39
7.34
PO2
PCO2
pH
PO2
PCO2
pH
PO2
PCO2
pH
CONTROL
HYPOVENT.
RECOVERY
ARTERIAL
VENOUS

FIGURE 15

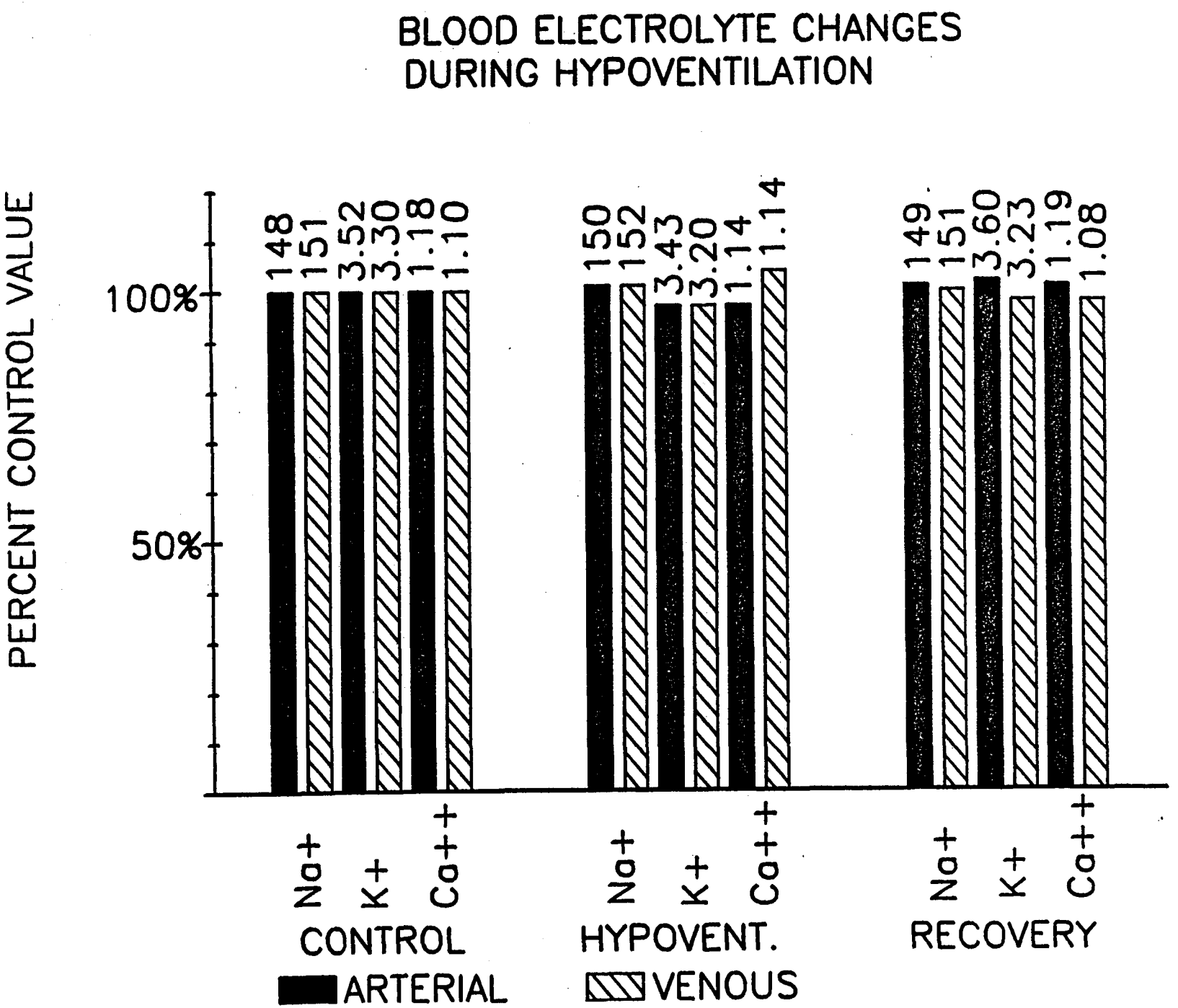

BLOOD ELECTROLYTE CHANGES
DURING HYPOVENTILATION
PERCENT CONTROL VALUE
100%
50%
148
151
3.52
3.30
1.18
1.10
150
152
3.43
3.20
1.14
1.14
149
151
3.60
3.23
1.19
1.08
Na+
K+
Ca++
Na+
K+
Ca++
Na+
K+
Ca++
CONTROL
HYPOVENT.
RECOVERY
ARTERIAL
VENOUS

FIGURE 16

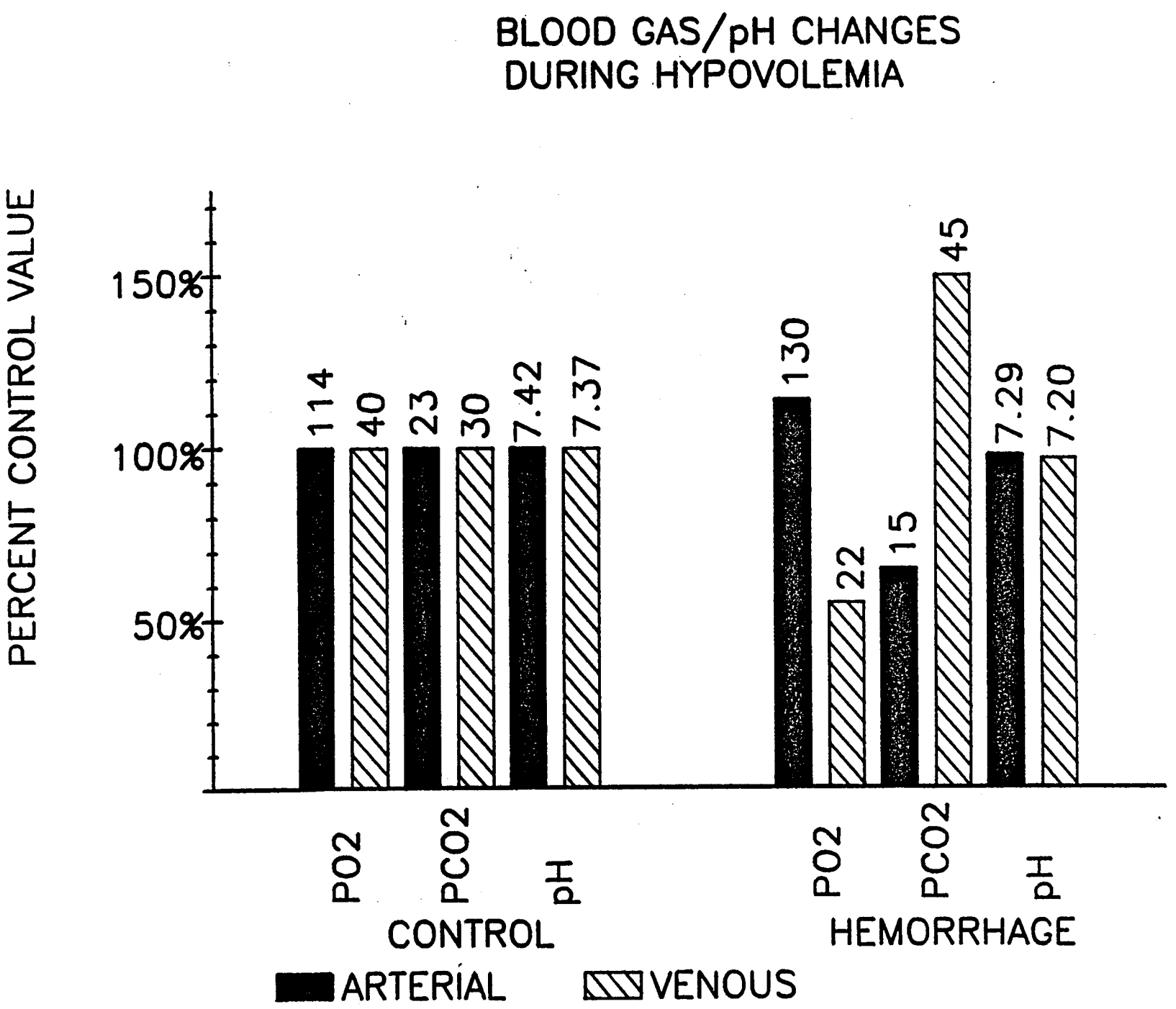
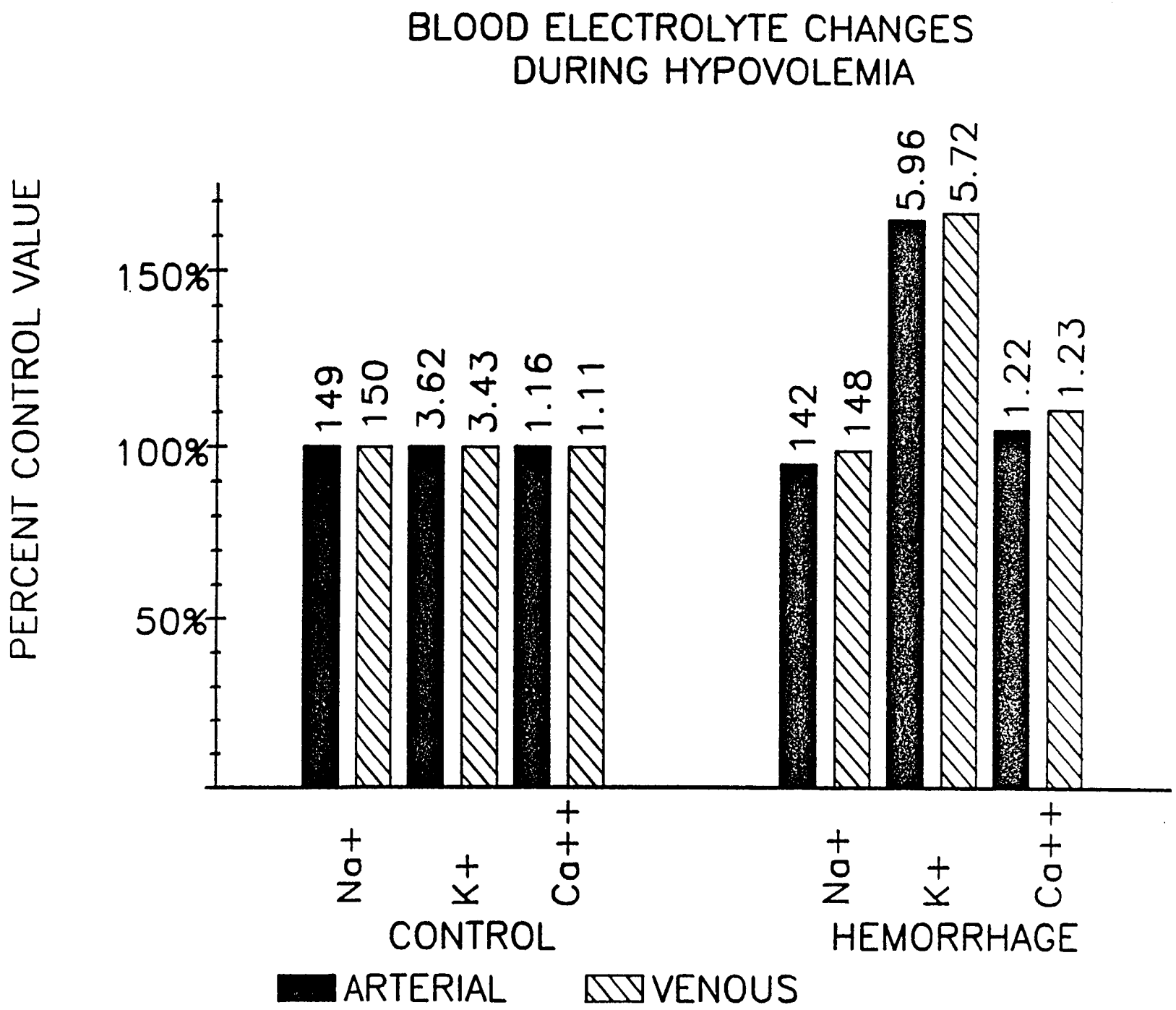

BLOOD GAS/pH CHANGES
DURING HYPOVOLEMIA
PERCENT CONTROL VALUE
150%
100%
50%
114
40
23
30
7.42
7.37
130
22
15
45
7.29
7.20
PO2
PCO2
pH
PO2
PCO2
pH
CONTROL
HEMORRHAGE
ARTERIAL
VENOUS

FIGURE 17


BLOOD ELECTROLYTE CHANGES
DURING HYPOVOLEMIA
PERCENT CONTROL VALUE
150%
100%
50%
149
150
3.62
3.43
1.16
1.11
142
148
5.96
5.72
1.22
1.23
Na+
K+
Ca++
Na+
K+
Ca++
CONTROL
HEMORRHAGE
ARTERIAL
VENOUS

D. TABLES

TABLE 1

ACC#	TOTAL PO2 NOVA	CORNING	Δ
201	27.9	27.6	0.3
202	28.1	28.5	0.4
203	73.5	69.4	4.1
204	21.5	20.1	1.4
205	34.9	32.8	2.1
207	26.2	25.1	1.1
208	57.7	62.1	4.4
209	22.0	23.2	1.2
210	27.0	24.8	2.2
211	28.4	26.8	1.6
212	21.1	21.9	0.8
213	24.1	28.1	4.0
215	24.0	23.2	0.8
216	32.5	28.3	4.2
217	68.3	63.9	4.4
218	24.7	22.6	2.1
219	36.3	37.0	0.7
301	118.4	113.8	4.6
302	126.4	119.3	7.1
303	105.7	104.6	1.1
304	111.4	113.3	1.9
305	115.8	120.3	4.5
306	120.1	116.5	3.6
307	117.2	128.1	10.9
308	113.0	113.6	0.6
317	115.9	115.8	0.1
318	141.4	133.8	7.6
319	95.4	104.3	8.9
320	108.2	111.1	2.9
321	102.8	105.4	2.6
322	128.1	129.4	1.3
323	90.1	88.5	1.6
324	93.9	97.8	3.9
325	90.6	91.9	1.3
335	114.2	120.4	6.2
336	136.9	132.8	4.1
337	81.3	82.1	0.8
338	111.2	122.7	11.5
339	110.9	115.9	5.0
340	111.4	118.4	7.0
341	98.1	101.4	3.3
342	118.0	122.0	4.0
309	82.3	84.6	2.3
310	124.4	127.7	3.3
311	91.0	87.6	3.4
312	88.1	87.3	0.8
313	84.8	95.0	10.2
314	106.0	114.7	8.7
315	93.2	100.5	7.3
316	81.2	84.7	3.5
326	142.3	146.6	4.3
327	132.9	134.4	1.5
328	120.7	128.1	7.4
330	103.8	97.1	6.7

TABLE 1 (con'd)

331	113.3	121.9	8.6
332	91.5	98.9	7.4
333	91.2	96.3	5.1
334	89.8	92.5	2.7
344	114.2	114.5	0.3
347	83.1	82.9	0.2
345	91.9	97.4	5.5
348	116.7	114.5	2.2
349	97.5	93.9	3.6
350	93.4	94.6	1.2
343	112.7	119.5	6.8
401	86.6	83.9	2.7
402	81.4	70.8	10.6
403	111.9	115.7	3.8
404	49.6	50.1	0.5
405	54.7	51.5	3.2
406	113.7	111.4	2.3
407	38.6	36.1	2.5
408	34.4	30.4	4.0
501	21.6	22.5	0.9
502	16.7	16.7	0.0
503	23.0	20.7	2.3
504	31.1	26.7	4.4
505	24.3	21.2	3.1
506	37.1	37.3	0.2
507	26.6	26.1	0.5
508	29.9	28.8	1.1
509	25.7	24.6	1.1
510	34.2	33.4	0.8
511	27.9	26.7	1.2
512	40.9	40.7	0.2
513	23.8	24.9	1.1
514	22.1	22.4	0.3
MEAN	76.5	77.3	3.4
S.E.	4.2	4.3	0.3

TABLE 2

ACC#	TOTAL PCO2 NOVA	CORNING	Δ
201	50.5	48.4	2.1
202	52.6	50.0	2.6
203	41.3	37.5	3.8
204	61.7	56.1	5.6
205	37.7	36.8	0.9
207	45.4	42.3	3.1
208	36.7	36.2	0.5
209	49.7	43.2	6.5
210	49.4	47.0	2.4
211	52.8	47.4	5.4
212	52.9	47.7	5.2
213	43.2	39.8	3.4
214	39.2	40.0	0.8
215	50.4	45.9	4.5
216	45.3	41.0	4.3
217	38.6	33.5	5.1
218	51.9	47.6	4.3
219	49.1	44.4	4.7
301	39.8	36.7	3.1
302	40.4	37.8	2.6
303	39.5	35.8	3.7
304	38.7	35.8	2.9
305	33.7	30.2	3.5
306	39.3	37.8	1.5
307	40.4	35.7	4.7
308	34.0	31.0	3.0
317	31.6	33.0	1.4
318	41.2	38.1	3.1
319	44.5	39.5	5.0
320	37.0	34.4	2.6
321	42.0	38.7	3.3
322	40.0	37.7	2.3
232	37.2	36.3	0.9
324	37.1	34.0	3.1
325	47.2	43.4	3.8
335	39.4	36.3	3.1
336	36.3	33.8	2.5
337	38.4	37.6	0.8
338	35.6	32.9	2.7
339	38.0	34.6	3.4
340	39.6	37.0	2.6
341	40.0	39.6	0.4
342	42.1	38.6	3.5
309	43.3	38.5	4.8
310	36.9	34.1	2.8
311	35.6	34.4	1.2
312	36.4	33.7	2.7
313	29.8	27.5	2.3
314	39.5	40.9	1.4
315	40.4	37.3	3.1
316	31.5	30.8	0.7
326	26.0	25.0	1.0
327	38.2	35.2	3.0
328	39.5	36.4	3.1

TABLE 2 (con'd)

329	31.1	31.8	0.7
330	39.8	36.1	3.7
331	38.6	37.2	1.4
332	35.9	34.5	1.4
333	35.4	35.1	0.3
334	43.9	39.6	4.3
344	39.6	37.5	2.1
347	35.9	33.0	2.9
345	33.4	31.2	2.2
348	30.8	30.4	0.4
349	31.1	30.3	0.8
350	41.2	38.1	3.1
346	34.1	36.4	2.3
343	29.8	29.8	0.0
401	37.3	37.0	0.3
402	39.0	33.1	5.9
403	39.4	36.6	2.8
404	35.8	33.4	2.4
405	45.0	43.6	1.4
406	34.4	35.9	1.5
407	74.7	68.5	6.2
408	44.9	45.8	0.9
409	31.3	32.5	1.2
501	52.5	48.8	3.7
502	49.5	45.6	3.9
503	56.1	52.5	3.6
504	48.1	46.7	1.4
505	53.0	50.9	2.1
506	49.0	47.3	1.7
507	53.7	50.9	2.8
508	56.3	54.1	2.2
509	61.3	59.2	2.1
510	45.3	47.4	2.1
511	55.1	53.2	1.9
512	56.4	54.6	1.8
513	57.0	55.1	1.9
514	61.4	59.5	1.9
MEAN	42.4	40.0	2.7
S.E.	0.9	0.8	0.2

TABLE 3

ACC#	TOTAL pH NOVA	CORNING	Δ
201	7.343	7.306	0.037
202	7.364	7.352	0.012
203	7.394	7.390	0.004
204	7.282	7.250	0.032
205	7.420	7.425	0.005
207	7.409	7.390	0.019
208	7.397	7.395	0.002
209	7.356	7.339	0.017
210	7.354	7.345	0.009
211	7.312	7.339	0.030
212	7.354	7.376	0.020
213	7.361	7.357	0.004
214	7.351	7.353	0.002
215	7.318	7.320	0.002
216	7.384	7.397	0.010
217	7.344	7.350	0.010
218	7.262	7.261	0.001
219	7.365	7.366	0.001
301	7.335	7.320	0.015
302	7.354	7.350	0.004
303	7.278	7.260	0.018
304	7.292	7.296	0.004
305	7.291	7.290	0.001
306	7.336	7.390	0.050
307	7.292	7.316	0.020
308	7.420	7.418	0.002
317	7.435	7.456	0.020
318	7.265	7.258	0.007
319	7.326	7.342	0.020
320	7.354	7.364	0.010
321	7.273	7.263	0.010
322	7.312	7.320	0.010
323	7.292	7.289	0.003
324	7.325	7.334	0.010
325	7.310	7.294	0.016
335	7.275	7.305	0.030
336	7.292	7.334	0.042
337	7.292	7.318	0.026
338	7.337	7.360	0.023
339	7.201	7.199	0.002
340	7.257	7.306	0.049
341	7.290	7.317	0.027
342	7.313	7.365	0.052
309	7.336	7.326	0.010
310	7.392	7.399	0.007
311	7.334	7.304	0.030
312	7.348	7.352	0.004
313	7.292	7.326	0.034
314	7.355	7.365	0.010
315	7.334	7.337	0.003
316	7.392	7.397	0.005
326	7.435	7.451	0.016
327	7.357	7.370	0.013
328	7.330	7.325	0.005

TABLE 3 (con'd)

329	7.360	7.346	0.014
330	7.320	7.324	0.004
331	7.417	7.452	0.035
332	7.312	7.307	0.005
333	7.352	7.350	0.002
334	7.340	7.327	0.013
344	7.339	7.345	0.006
347	7.343	7.335	0.008
345	7.299	7.299	0.000
348	7.384	7.403	0.019
349	7.296	7.263	0.033
350	7.304	7.292	0.012
346	7.415	7.403	0.012
343	7.449	7.473	0.024
401	7.394	7.397	0.003
402	7.378	7.434	0.056
403	7.434	7.412	0.022
404	7.453	7.441	0.012
405	7.443	7.456	0.013
406	7.449	7.476	0.027
407	7.288	7.307	0.019
408	7.345	7.387	0.042
409	7.463	7.479	0.016
501	7.309	7.305	0.004
502	7.315	7.317	0.002
503	7.300	7.296	0.004
504	7.317	7.329	0.012
505	7.320	7.315	0.005
506	7.334	7.328	0.006
507	7.319	7.353	0.034
508	7.301	7.301	0.000
509	7.263	7.278	0.015
510	7.349	7.385	0.036
511	7.293	7.279	0.014
512	7.286	7.317	0.031
513	7.299	7.298	0.001
514	7.287	7.313	0.026
MEAN	7.339	7.346	0.016
S.E.	0.005	0.006	0.001

TABLE 4

ACC#	TOTAL Hct NOVA	SPIN	Δ
201	45	38	7
202	49	42	7
203	45	43	2
204	48	45	3
205	41	42	1
207	44	44	0
208	40	45	5
209	45	46	1
210	44	43	1
211	43	43	0
212	42	42	0
213	47	45	2
215	49	49	0
216	45	42	3
218	46	47	1
219	41	40	1
301	32	24	8
302	26	24	2
303	45	45	0
304	31	28	3
305	25	21	4
306	23	20	3
307	30	29	1
308	28	27	1
317	28	22	6
318	28	26	2
320	26	24	2
321	32	33	1
322	30	30	0
323	33	30	3
324	40	34	6
325	43	38	5
335	26	26	0
336	28	28	0
337	23	21	2
338	28	28	0
339	42	44	2
340	30	30	0
341	24	23	1
342	25	23	2
309	31	28	3
310	31	26	5
311	58	56	2
312	32	30	2
313	29	24	5
314	28	23	5
315	31	30	1
316	30	28	2
326	27	29	2
327	32	30	2
328	37	37	0
329	27	24	3
330	46	37	9
331	33	31	2

TABLE 4 (con'd)

332	33	32	1
333	33	31	2
334	45	43	2
344	28	26	2
347	36	36	0
345	27	24	3
348	31	30	1
349	57	57	0
350	31	30	1
346	30	20	10
343	27	24	3
401	41	42	1
402	28	25	3
403	40	41	1
404	41	43	2
405	37	36	1
406	37	37	0
407	54	53	1
408	38	38	0
409	35	36	1
501	45	45	0
502	40	40	0
503	47	48	1
504	42	43	1
505	47	49	2
506	43	44	1
507	42	43	1
508	44	46	2
509	41	41	0
510	49	50	1
511	45	47	2
512	43	46	3
513	43	44	1
514	47	47	0
MEAN	37.03	35.73	2.06
S.E.	0.90	1.00	0.22

TABLE 5

ACC#	TOTAL K+ NOVA	FLAME	Δ
201	4.87	4.40	0.47
202	3.61	3.75	0.14
204	4.68	5.10	0.42
205	3.77	3.90	0.13
207	4.55	4.30	0.25
209	4.47	4.80	0.33
211	3.61	3.90	0.29
212	4.49	4.80	0.31
213	5.03	4.80	0.23
215	4.78	5.10	0.32
216	3.47	3.90	0.43
218	4.49	4.80	0.31
219	4.21	4.40	0.19
301	5.76	5.95	0.19
302	5.50	5.70	0.20
303	4.85	5.15	0.30
304	4.81	5.00	0.19
305	5.67	5.80	0.13
306	4.77	5.10	0.33
307	4.83	4.95	0.12
308	5.36	5.35	0.01
317	4.45	4.50	0.05
318	4.68	4.70	0.02
319	5.29	5.60	0.31
320	4.24	4.30	0.06
321	4.77	5.00	0.23
322	4.80	5.00	0.20
323	5.97	6.00	0.03
324	4.73	4.80	0.07
325	4.25	4.30	0.05
335	4.29	4.50	0.21
336	5.46	5.80	0.34
337	6.09	6.50	0.41
338	5.44	5.90	0.46
339	6.01	6.30	0.29
340	4.50	4.70	0.20
341	6.05	6.40	0.35
342	5.07	5.40	0.33
309	3.56	3.70	0.14
310	3.53	3.70	0.17
311	3.80	4.00	0.20
312	3.69	3.80	0.11
313	3.51	3.80	0.29
314	3.27	3.60	0.33
315	3.66	3.90	0.24
316	3.03	3.10	0.07
326	3.05	3.10	0.05
327	3.42	3.50	0.08
328	3.55	3.80	0.25
329	2.99	3.00	0.01
330	3.59	3.50	0.09
331	3.43	3.70	0.27
332	3.87	3.90	0.03
333	3.35	3.50	0.15

TABLE 5 (con'd)

334	3.57	3.40	0.17
344	3.31	3.50	0.19
347	3.58	3.80	0.22
345	3.69	4.00	0.31
348	3.24	3.40	0.16
349	4.04	4.20	0.16
350	3.63	3.80	0.17
346	3.87	4.10	0.23
343	3.57	3.80	0.23
402	3.84	3.80	0.04
404	4.03	3.80	0.23
405	2.85	3.00	0.15
406	3.88	3.80	0.08
407	5.04	5.20	0.16
408	4.90	5.20	0.30
409	4.96	5.50	0.54
501	4.07	4.20	0.13
502	4.61	4.30	0.31
503	5.04	4.60	0.44
504	4.01	3.90	0.11
505	4.51	4.30	0.21
506	3.90	4.30	0.40
507	4.50	4.40	0.10
508	4.66	4.70	0.04
509	4.46	3.90	0.56
510	4.13	4.60	0.47
511	4.22	4.70	0.48
512	4.50	4.50	0.00
513	4.07	4.40	0.33
514	4.66	4.90	0.24
MEAN	4.31	4.46	0.22
S.E.	0.09	0.09	0.01

TABLE 6

ACC#	TOTAL Na+ NOVA	FLAME	Δ
201	146.5	142.6	3.9
202	142.8	142.8	0.0
204	147.1	145.1	2.0
205	137.3	134.0	3.3
207	140.5	140.0	0.5
209	143.0	141.0	2.0
210	139.9	141.0	1.1
211	142.5	148.0	5.5
212	144.1	148.0	3.9
213	137.3	127.0	10.3
215	147.2	145.0	2.2
216	144.0	137.0	7.0
218	146.0	146.0	0.0
219	133.1	135.0	1.9
301	140.6	138.0	2.6
302	144.3	142.0	2.3
303	142.1	139.0	3.1
304	145.0	141.5	3.5
305	134.7	132.5	2.2
306	143.7	140.5	3.2
307	142.8	138.5	4.3
308	139.0	137.5	1.5
317	143.5	142.0	1.5
318	142.5	140.0	2.5
319	137.8	133.0	4.8
320	134.7	132.0	2.7
321	139.4	136.0	3.4
322	147.8	144.0	3.8
323	134.6	130.0	4.6
324	144.0	140.0	4.0
325	142.4	136.0	6.4
335	141.9	142.0	0.1
336	142.2	142.0	0.2
337	139.9	140.0	0.1
338	139.6	141.0	1.4
339	142.2	140.0	2.2
340	144.3	142.0	2.3
341	143.8	145.0	1.2
342	142.7	141.0	1.7
309	142.6	140.0	2.6
310	142.6	141.0	1.6
311	144.0	138.0	6.0
312	144.1	140.0	4.1
313	141.6	137.0	4.6
314	143.2	139.0	4.2
315	141.8	138.0	3.8
316	141.9	139.0	2.9
326	142.3	139.0	3.3
328	142.4	138.0	4.4
329	138.5	135.0	3.5
330	144.6	138.0	6.6
331	144.3	140.0	4.3
333	144.3	140.0	4.3
344	141.3	138.0	3.3

TABLE 6 (con'd)

347	144.6	140.0	4.6
345	143.4	141.0	2.4
348	141.5	138.0	3.5
350	145.9	140.0	5.9
346	143.4	141.0	2.4
343	140.1	138.0	2.1
402	135.2	137.0	1.8
404	139.9	137.0	2.9
405	140.4	138.0	2.4
406	141.0	136.0	5.0
407	144.0	145.0	1.0
408	145.8	146.0	0.2
409	138.8	139.0	0.2
501	143.7	142.0	1.7
502	144.2	141.0	3.2
503	144.4	141.0	3.4
504	143.2	140.0	3.2
505	146.1	143.0	3.1
506	146.0	147.0	1.0
507	144.9	142.0	2.9
508	145.9	141.0	4.9
509	145.4	141.0	4.4
510	144.6	140.0	4.6
511	146.5	141.0	5.5
512	145.0	143.0	2.0
513	146.2	145.0	1.2
514	138.6	135.0	3.6
MEAN	142.4	139.8	3.1
S.E.	0.3	0.4	0.2

TABLE 7

ACC#	TOTAL Ca++ NOVA	COLOR	Δ
201	1.20	2.23	1.03
202	1.19	2.40	1.21
204	1.26	2.55	1.29
205	1.11	2.18	1.07
207	1.22	2.33	1.11
209	1.24	2.40	1.16
210	1.25	2.40	1.15
211	1.25	2.18	0.93
212	1.46	2.76	1.30
213	1.28	2.18	0.90
215	1.34	2.40	1.06
216	1.26	2.40	1.14
218	1.30	2.43	1.13
219	1.22	2.30	1.08
301	1.26	2.45	1.19
302	1.17	2.40	1.23
303	1.20	2.45	1.25
304	1.22	2.40	1.18
305	0.99	2.00	1.01
306	1.15	2.33	1.18
307	1.30	2.43	1.13
308	1.08	2.03	0.95
317	1.29	2.63	1.34
318	1.24	2.28	1.04
319	1.14	2.23	1.09
320	1.07	2.13	1.06
321	1.17	2.20	1.03
322	1.24	2.40	1.16
323	1.31	2.65	1.34
324	1.10	2.18	1.08
325	1.16	2.30	1.14
309	1.35	2.55	1.20
310	1.33	2.70	1.37
311	1.39	3.05	1.66
312	1.31	2.63	1.32
313	1.27	2.48	1.21
314	1.31	2.55	1.24
315	1.35	2.58	1.23
316	1.23	2.25	1.02
326	1.42	2.68	1.26
327	1.28	2.55	1.27
328	1.38	2.58	1.20
329	1.29	2.35	1.06
330	1.36	2.80	1.44
331	1.32	2.70	1.38
332	1.40	2.70	1.30
333	1.27	2.40	1.13
334	1.31	2.60	1.29
402	1.13	1.95	0.82
404	1.10	2.10	1.00
405	1.19	2.52	1.33
406	1.17	2.30	1.13
407	1.24	2.45	1.21
408	1.28	2.30	1.02

TABLE 7 (con'd)

409	1.05	2.20	1.15
501	1.43	2.32	0.89
502	1.41	2.38	0.97
503	1.44	2.36	0.92
504	1.34	2.36	1.02
505	1.39	2.38	0.99
506	1.39	2.46	1.07
507	1.39	2.42	1.03
508	1.41	2.40	0.99
509	1.41	2.40	0.99
510	1.36	2.52	1.16
511	1.33	2.32	0.99
512	1.39	2.46	1.07
513	1.40	2.50	1.10
514	1.33	2.42	1.09
MEAN	1.27	2.41	1.14
S.E.	0.01	0.02	0.02

TABLE 8

ACC#	TOTAL Hbc NOVA	OSM2	Δ
201	15.0	13.9	1.1
202	16.5	15.9	0.6
203	15.0	13.0	2.0
204	14.6	14.6	0.0
205	13.8	13.3	0.5
207	14.7	14.8	0.1
208	13.5	12.7	0.8
209	14.9	15.1	0.2
210	14.6	14.1	0.5
211	14.2	13.6	0.6
212	14.1	13.5	0.6
213	15.7	13.8	1.9
214	14.9	15.6	0.7
215	16.2	16.2	0.0
216	14.9	14.0	0.9
218	15.2	14.1	1.1
219	13.7	12.7	1.0
301	10.6	7.9	2.7
	8.8	7.7	1.1
303	14.9	13.4	1.5
304	10.2	9.4	0.8
305	8.3	6.7	1.6
306	7.7	6.6	1.1
307	10.1	8.9	1.2
308	9.4	8.4	1.0
317	9.3	7.8	1.5
318	9.2	8.1	1.1
320	8.7	7.3	1.4
321	10.7	8.8	1.9
322	10.1	9.1	1.0
323	11.1	9.6	1.5
324	13.3	9.5	3.8
325	14.4	12.5	1.9
335	8.8	8.1	0.7
336	9.2	5.4	3.8
337	7.8	6.5	1.3
338	9.4	8.9	0.5
339	13.9	13.0	0.9
340	9.9	9.6	0.3
341	8.1	7.2	0.9
342	8.2	6.8	1.4
309	10.4	8.2	2.2
310	10.3	8.5	1.8
311	19.2	16.4	2.8
312	10.5	9.9	0.6
313	9.8	8.0	1.8
314	9.2	6.9	2.3
315	10.4	9.2	1.2
316	9.9	8.4	1.5
326	9.1	7.5	1.6
327	10.6	9.1	1.5
328	12.4	12.1	0.3
329	8.9	7.3	1.6
330	15.5	11.6	3.9

TABLE 8 (con'd)

331	10.9	9.7	1.2
332	11.1	9.6	1.5
333	10.9	9.3	1.6
334	15.2	13.7	1.5
344	9.3	8.2	1.1
347	11.9	8.0	3.9
345	9.0	7.5	1.5
348	10.4	9.0	1.4
349	19.1	16.8	2.3
350	10.4	9.1	1.3
346	10.0	7.5	2.5
343	8.9	6.8	2.1
401	13.6	13.6	0.0
402	9.4	8.1	1.3
403	13.4	12.1	1.3
404	13.6	12.5	1.1
405	12.5	10.5	2.0
406	12.4	11.4	1.0
407	18.1	15.8	2.3
408	12.7	12.0	0.7
409	11.7	10.8	0.9
501	14.8	14.4	0.4
502	13.3	12.7	0.6
503	15.7	15.6	0.1
504	14.1	14.1	0.0
505	15.7	15.6	0.1
506	14.5	14.3	0.2
507	14.1	15.1	1.0
508	14.6	15.2	0.6
509	13.5	14.5	1.0
510	16.4	17.2	0.8
511	15.0	15.0	0.0
512	14.4	15.1	0.7
513	14.4	15.0	0.6
514	15.6	16.0	0.4
MEAN	12.4	11.3	1.2
S.E.	0.3	0.3	0.1

TABLE 9

ACC#	TOTAL O2Sat NOVA	OSM2	Δ
201	50.3	50.1	0.2
202	50.6	49.6	1.0
203	94.5	97.6	3.1
204	28.2	25.4	2.8
205	68.6	67.4	1.2
207	48.3	45.8	2.5
208	89.7	96.5	6.8
209	34.0	50.6	16.6
210	46.4	47.8	1.4
211	46.8	42.5	4.3
212	31.3	33.2	1.9
213	40.2	36.1	4.1
215	37.1	30.1	7.0
216	61.0	56.3	4.7
218	35.5	32.0	3.5
219	66.6	69.0	2.4
301	98.4	99.5	1.1
302	98.7	100.0	1.3
303	97.3	99.7	2.4
304	97.8	100.0	2.2
305	98.1	96.2	1.9
306	98.6	98.9	0.3
307	98.1	98.6	0.5
308	98.6	100.0	1.4
317	98.7	100.0	1.3
318	98.8	100.0	1.2
319	96.8	100.0	3.2
320	98.0	99.7	1.7
321	97.0	99.4	2.4
322	98.6	100.0	1.4
323	96.0	96.3	0.3
324	96.7	99.8	3.1
325	96.1	99.2	3.1
335	97.8	97.9	0.1
336	98.8	100.0	1.2
337	94.6	91.2	3.4
338	98.1	98.4	0.3
339	97.1	97.6	0.5
340	97.5	100.0	2.5
341	96.8	99.6	2.8
342	98.2	100.0	1.8
309	95.2	99.1	3.9
310	98.8	100.0	1.2
311	96.5	97.3	0.8
312	96.3	98.1	1.8
313	95.3	95.5	0.2
314	97.9	99.0	1.1
315	96.7	98.0	1.3
316	96.0	96.4	0.4
326	99.3	100.0	0.7
327	98.9	100.0	1.1
328	98.4	100.0	1.6
329	99.4	98.4	1.0
330	97.5	99.8	2.3

TABLE 9 (con'd)

331	98.5	99.3	0.8
332	96.4	98.5	2.1
333	96.7	99.5	2.8
334	96.3	100.0	3.7
344	98.2	99.8	1.6
347	95.6	95.8	0.2
345	96.3	95.2	1.1
348	98.6	98.6	0.0
349	96.9	97.3	0.4
350	96.4	98.7	2.3
346	99.4	100.0	0.6
343	98.7	100.0	1.3
401	96.6	96.9	0.3
402	95.7	95.6	0.1
403	98.5	100.0	1.5
404	86.7	93.5	6.8
405	88.9	89.1	0.2
406	98.7	98.6	0.1
407	63.6	62.8	0.8
408	62.5	54.5	8.0
409	96.7	96.7	0.0
501	30.4	33.8	3.4
502	19.9	17.5	2.4
503	33.0	35.6	2.6
504	53.6	54.6	1.0
505	37.6	38.5	0.9
506	66.2	67.9	1.7
507	43.0	45.0	2.0
508	49.2	37.5	11.7
509	37.1	40.2	3.1
510	62.2	64.1	1.9
511	44.5	45.9	1.4
512	68.7	69.1	0.4
513	35.0	34.7	0.3
MEAN	80.4	80.4	2.2
S.E.	2.7	2.7	0.3

TABLE 10

ACC#	TOTAL O2Ct NOVA	OSM2	Δ
201	10.4	9.7	0.7
202	11.5	11.0	0.5
203	19.6	17.6	2.0
204	5.7	5.2	0.5
205	13.1	12.5	0.6
207	9.9	9.4	0.5
208	16.7	17.1	0.4
209	7.0	10.7	3.7
210	9.4	9.4	0.0
211	9.2	8.1	1.1
212	6.1	6.2	0.1
213	8.7	6.9	1.8
215	8.3	6.8	1.5
216	12.6	10.9	1.7
218	7.5	6.3	1.2
219	12.6	12.2	0.4
301	14.4	10.9	3.5
302	12.1	10.7	1.4
303	20.2	18.6	1.6
304	13.8	13.1	0.7
305	11.3	8.0	3.3
306	10.5	9.1	1.4
307	13.7	12.2	1.5
308	12.8	11.7	1.1
317	12.7	10.8	1.9
318	12.5	11.3	1.2
319	26.2	20.1	6.1
320	11.8	10.1	1.7
321	14.3	12.2	2.1
322	13.9	12.6	1.3
323	14.8	12.9	1.9
324	17.9	13.2	4.7
325	19.2	17.2	2.0
335	11.9	11.0	0.9
336	12.6	7.5	5.1
337	10.2	8.2	2.0
338	12.7	12.2	0.5
339	18.8	17.6	1.2
340	13.3	13.3	0.0
341	10.9	10.0	0.9
342	11.1	9.5	1.6
309	13.7	11.3	2.4
310	14.1	12.1	2.0
311	25.7	22.2	3.5
312	14.1	13.5	0.6
313	12.9	10.6	2.3
314	12.5	9.5	3.0
315	14.0	12.5	1.5
316	13.2	11.3	1.9
326	12.5	10.4	2.1
327	14.5	13.5	1.0
328	16.9	16.8	0.1
329	12.2	10.0	2.2
330	20.9	16.1	4.8

TABLE 10 (con'd)

331	14.9	13.4	1.5
332	14.8	13.1	1.7
333	14.5	12.9	1.6
334	20.3	19.0	1.3
344	12.7	11.4	1.3
347	15.8	10.7	5.1
345	12.1	9.9	2.2
348	14.2	12.3	1.9
349	25.7	22.7	3.0
350	13.9	12.5	1.4
346	13.8	10.6	3.2
343	12.2	9.5	2.7
401	18.2	18.7	0.5
402	12.5	10.8	1.7
403	18.2	16.8	1.4
404	16.3	16.3	0.0
405	15.4	13.0	2.4
406	17.0	15.4	1.6
407	15.9	13.8	2.1
408	11.0	9.2	1.8
409	15.7	14.6	1.1
501	6.2	6.8	0.6
502	3.6	3.2	0.4
503	7.1	7.8	0.7
504	10.5	11.0	0.5
505	8.2	8.5	0.3
506	13.3	13.5	0.2
507	8.4	9.4	1.0
508	10.0	8.0	2.0
509	6.9	8.1	1.2
510	14.1	15.3	1.2
511	9.2	9.6	0.4
512	13.7	14.5	0.8
513	6.9	7.3	0.4
MEAN	13.2	11.9	1.6
S.E.	0.4	0.4	0.1

TABLE 11

ACC#	TOTAL HCO3 NOVA	CORNING	Δ
201	27.7	24.1	3.6
202	30.2	27.6	2.6
203	25.4	21.4	4.0
204	29.3	24.5	4.8
205	24.6	24.1	0.5
207	28.8	25.5	3.3
208	22.7	22.1	0.6
209	28.0	23.2	4.8
210	27.7	25.6	2.1
211	26.8	25.5	1.3
212	29.6	27.9	1.7
213	24.6	22.3	2.3
214	21.8	22.2	0.4
215	26.0	23.6	2.4
216	27.2	25.1	2.1
217	21.1	18.5	2.6
218	23.6	21.4	2.2
219	28.2	25.3	2.9
301	21.4	18.9	2.5
302	22.6	20.9	1.7
303	18.6	16.0	2.6
304	18.8	17.4	1.4
305	16.4	14.7	1.7
306	22.6	22.8	0.2
307	19.7	18.2	1.5
308	22.2	20.0	2.2
317	21.4	23.2	1.8
318	18.8	17.0	1.8
319	23.4	21.4	2.0
320	20.7	19.5	1.2
321	19.5	17.5	2.0
322	20.4	19.4	1.0
323	18.1	17.4	0.7
324	19.5	18.0	1.5
325	23.9	21.0	2.9
335	18.4	18.0	0.4
336	17.6	17.9	0.3
337	18.7	19.3	0.6
338	19.2	18.6	0.6
339	15.0	13.4	1.6
340	17.8	18.4	0.6
341	19.3	20.2	0.9
342	21.4	22.0	0.6
309	23.3	20.1	3.2
310	22.6	20.6	2.0
311	19.1	17.0	2.1
312	20.1	18.7	1.4
313	14.5	14.3	0.2
314	22.2	23.3	1.1
315	21.6	20.0	1.6
316	19.3	18.9	0.4
326	17.6	17.4	0.2
327	21.6	20.3	1.3
328	21.0	18.9	2.1

TABLE 11 (con'd)

329	17.7	17.3	0.4
330	20.7	18.8	1.9
331	25.0	25.9	0.9
332	18.2	17.2	1.0
333	19.7	19.3	0.4
334	23.8	20.7	3.1
344	21.4	20.4	1.0
347	19.6	17.6	2.0
345	16.5	15.3	1.2
348	18.5	18.9	0.4
349	15.3	13.5	1.8
350	20.5	18.4	2.1
346	22.0	22.6	0.6
343	20.8	21.8	1.0
401	22.9	22.7	0.2
402	23.1	22.1	1.0
403	26.5	23.3	3.2
404	25.2	22.7	2.5
405	30.9	30.6	0.3
406	24.0	26.5	2.5
407	35.9	34.2	1.7
408	24.7	27.5	2.8
409	22.5	24.1	1.6
501	26.5	24.3	2.2
502	25.3	23.3	2.0
503	27.8	25.5	2.3
504	24.7	24.5	0.2
505	27.5	25.9	1.6
506	26.2	24.7	1.5
507	27.8	28.2	0.4
508	28.0	26.6	1.4
509	27.8	27.6	0.2
510	25.1	28.3	3.2
511	26.9	24.9	2.0
512	27.0	27.9	0.9
513	28.1	26.9	1.2
514	29.5	30.1	0.6
MEAN	22.9	21.8	1.6
S.E.	0.4	0.4	0.1

TABLE 12.

PO2 - PREDIALYSIS

ACC#	PT#	NOVA	CORNING	Δ
301	1	118.4	113.8	4.6
302	2	126.4	119.3	7.1
303	3	105.7	104.6	1.1
304	4	111.4	113.3	1.9
305	5	115.8	120.3	4.5
306	6	120.1	116.5	3.6
307	7	117.2	128.1	10.9
308	8	113.0	113.6	0.6
317	9	115.9	115.8	0.1
318	10	141.4	133.8	7.6
319	11	95.4	104.3	8.9
320	12	108.2	111.1	2.9
321	13	102.8	105.4	2.6
322	14	128.1	129.4	1.3
323	15	90.1	88.5	1.6
324	16	93.9	97.8	3.9
325	17	90.6	91.9	1.4
335	7	114.2	120.4	6.2
336	1	136.9	132.8	4.1
337	5	81.3	82.1	0.8
338	8	111.2	122.7	11.5
339	3	110.9	115.9	5.0
340	4	111.4	118.4	7.0
341	2	98.1	101.4	3.3
342	6	118.0	122.0	4.0
MEAN		111.1	112.9	4.3
S.E.		2.9	2.6	0.6

PO2 - POSTDIALYSIS

ACC#	PT#	NOVA	CORNING	Δ
309	1	82.3	84.6	2.3
310	2	124.4	127.7	3.3
311	3	91.0	87.6	2.4
312	4	88.1	87.3	0.4
313	5	84.8	95.0	10.2
314	6	106.0	114.7	8.7
315	7	93.2	100.5	7.3
316	8	81.2	84.7	3.5
326	9	142.3	146.6	4.3
327	10	132.9	134.4	1.5
328	11	120.7	128.1	7.4
330	13	103.8	97.1	6.7
331	14	113.3	121.9	8.6
332	15	91.5	98.9	7.4
333	16	91.2	96.3	5.1
334	17	89.8	92.5	3.8
344	7	114.2	114.5	0.3
347	1	83.1	82.9	0.2
345	5	91.9	97.4	5.5
348	8	116.7	114.5	2.2
349	3	97.5	93.9	3.6
350	4	93.4	94.6	1.2
343	6	112.7	119.5	7.8
MEAN		105.0	102.0	4.3
S.E.		3.7	3.6	0.6

TABLE 13.

Hct - PREDIALYSIS

ACC#	PT#	NOVA	SPIN	Δ
301	1	32	24	6
302	2	26	24	2
303	3	45	45	0
304	4	31	28	3
305	5	25	21	4
306	6	23	20	3
307	7	30	29	1
308	8	28	27	1
317	9	28	22	6
318	10	28	26	2
320	12	26	24	2
321	13	32	33	1
322	14	30	30	0
323	15	33	30	3
324	16	40	34	6
325	17	43	38	5
335	7	26	26	0
336	1	28	28	0
337	5	23	21	2
338	8	28	28	0
339	3	42	44	2
340	4	30	30	0
341	2	24	23	1
342	6	25	23	2
MEAN		31.4	28.8	2.1
S.E.		1.3	1.4	0.4

Hct - POSTDIALYSIS

ACC#	PT#	NOVA	SPIN	Δ
309	1	31	28	3
310	2	31	26	5
311	3	58	56	2
312	4	32	30	2
313	5	29	24	5
314	6	28	23	5
315	7	31	30	1
316	8	30	28	2
326	9	27	29	2
327	10	32	30	2
328	11	37	37	0
329	12	27	24	3
330	13	46	37	9
331	14	33	31	2
332	15	33	32	1
333	16	33	31	2
334	17	45	43	2
344	7	28	26	2
347	1	36	36	0
345	5	27	24	3
348	8	31	30	1
349	3	57	57	0
350	4	31	30	1
346	2	30	20	10
343	6	27	24	3
MEAN		34	31.4	2.7
S.E.		1.7	1.8	0.5

TABLE 14.

Hbc - PREDIALYSIS

ACC#	PT#	NOVA	OSM2	Δ
301	1	10.6	7.9	2.7
302	2	8.8	7.7	1.1
303	3	14.9	13.4	1.5
304	4	10.2	9.4	0.8
305	5	8.3	6.7	1.6
306	6	7.7	6.6	1.1
307	7	10.1	8.9	1.2
308	8	9.4	8.4	1.0
317	9	9.3	7.8	1.5
318	10	9.2	8.1	1.1
320	12	8.7	7.3	1.4
321	13	10.7	8.8	1.9
322	14	10.1	9.1	1.0
323	15	11.1	9.6	1.5
324	16	13.3	9.5	3.8
325	17	14.4	12.5	1.9
335	7	8.8	8.1	0.7
336	1	9.2	5.4	3.8
337	5	7.8	6.5	1.3
338	8	9.4	8.9	0.5
339	3	13.9	13.0	0.9
340	4	9.9	9.6	0.3
341	2	8.1	7.2	0.9
342	6	8.2	6.8	1.4
MEAN		10.5	8.6	1.5
S.E.		2.1	1.8	0.2

Hbc - POSTDIALYSIS

ACC#	PT#	NOVA	OSM2	Δ
309	1	10.4	8.2	2.2
310	2	10.3	8.5	1.8
311	3	19.2	16.4	2.8
312	4	10.5	9.9	0.6
313	5	9.8	8.0	1.8
314	6	9.2	6.9	2.3
315	7	10.4	9.2	1.2
316	8	9.9	8.4	1.5
326	9	9.1	7.5	1.6
327	10	10.6	9.1	1.5
328	11	12.4	12.1	0.3
329	12	8.9	7.3	1.6
330	13	15.5	11.6	3.9
331	14	10.9	9.7	1.2
332	15	11.1	9.6	1.5
333	16	10.9	9.3	1.6
334	17	15.2	13.7	1.5
344	7	9.3	8.2	1.1
347	1	11.9	8.0	2.9
345	5	9.0	7.5	1.5
348	8	10.4	9.0	1.4
349	3	19.1	16.8	2.3
350	4	10.4	9.1	1.3
346	2	10.0	7.5	2.5
343	6	8.9	6.8	2.1
MEAN		11.3	9.5	1.8
S.E.		0.6	0.5	0.1

TABLE 15.

O2Sat - PREDIALYSIS

ACC#	PT#	NOVA	OSM2	Δ
301	1	98.4	99.5	1.1
302	2	98.7	100.0	1.3
303	3	97.3	99.7	2.4
304	4	97.8	100.0	2.2
305	5	98.1	96.2	1.9
306	6	98.6	98.9	0.3
307	7	98.1	98.6	0.5
308	8	98.6	100.0	1.4
317	9	98.7	100.0	1.3
318	10	98.8	100.0	1.2
319	11	96.8	100.0	2.2
320	12	98.0	99.7	1.7
321	13	97.0	99.4	2.4
322	14	98.6	100.0	1.4
323	15	96.0	96.3	0.3
324	16	96.7	99.8	3.1
325	17	96.1	99.2	3.1
335	7	97.8	97.9	0.1
336	1	98.8	100.0	1.2
337	5	94.6	91.2	3.4
338	8	98.1	98.4	0.3
339	3	97.1	97.6	0.5
340	4	97.5	100.0	2.5
341	2	96.8	99.6	2.8
342	6	98.2	100.0	1.8
MEAN		97.7	98.9	1.6
S.E.		0.2	0.4	0.2

O2Sat - POSTDIALYSIS

ACC#	PT#	NOVA	OSM2	Δ
309	1	95.2	99.1	3.9
310	2	98.8	100.0	1.2
311	3	96.5	97.3	0.8
312	4	96.3	98.1	1.8
313	5	95.3	95.5	0.2
314	6	97.9	99.0	1.1
315	7	96.7	98.0	1.3
316	8	96.0	96.4	0.4
326	9	99.3	100.0	0.7
327	10	98.9	100.0	1.1
328	11	98.4	100.0	1.6
329	12	99.4	98.4	1.0
330	13	97.5	99.8	2.3
331	14	98.5	99.3	0.8
332	15	96.4	98.5	2.1
333	16	96.7	99.5	2.8
334	17	96.3	100.0	3.7
344	7	98.2	99.8	1.6
347	1	95.6	95.8	0.2
345	5	96.3	95.2	1.1
348	8	98.6	98.6	0.0
349	3	96.9	97.3	0.4
350	4	96.4	98.7	2.3
346	2	99.4	100.0	0.6
343	6	98.7	100.0	1.3
MEAN		97.4	98.6	1.4
S.E.		0.3	0.3	0.2

TABLE 16.

O2Ct -PREDIALYSIS

ACC#	PT#	NOVA	OSM2	Δ
301	1	14.4	10.9	4.5
302	2	12.1	10.7	1.4
303	3	20.2	18.6	1.6
304	4	13.8	13.1	0.7
305	5	11.3	8.0	3.3
306	6	10.5	9.1	1.4
307	7	13.7	12.2	1.5
308	8	12.8	11.7	1.1
317	9	12.7	10.8	1.9
318	10	12.5	11.3	1.2
319	11	26.2	20.1	6.1
320	12	11.8	10.1	1.7
321	13	14.3	12.2	2.1
322	14	13.9	12.6	1.3
323	15	14.8	12.9	1.9
324	16	17.9	13.2	4.7
325	17	19.2	17.2	2.0
335	7	11.9	11.0	0.9
336	1	12.6	7.5	5.1
337	5	10.2	8.2	2.0
338	8	12.7	12.2	0.5
339	3	18.8	17.6	1.2
340	4	13.3	13.3	0.0
341	2	10.9	10.0	0.9
342	6	11.1	9.5	1.6
MEAN		14.1	12.2	2.0
S.E.		0.7	0.6	0.3

O2Ct - POSTDIALYSIS

ACC#	PT#	NOVA	OSM2	Δ
309	1	13.7	11.3	2.4
310	2	14.1	12.1	2.0
311	3	25.7	22.2	3.5
312	4	14.1	13.5	0.6
313	5	12.9	10.6	2.3
314	6	12.5	9.5	3.0
315	7	14.0	12.5	1.5
316	8	13.2	11.3	1.9
326	9	12.5	10.4	2.1
327	10	14.5	13.5	1.0
328	11	16.9	16.8	0.1
329	12	12.2	10.0	2.2
330	13	20.9	16.1	4.8
331	14	14.9	13.4	1.5
332	15	14.8	13.1	1.7
333	16	14.5	12.9	2.6
334	17	20.3	19.0	0.7
344	7	12.7	11.4	1.3
347	1	15.8	10.7	5.1
345	5	12.1	9.9	2.2
348	8	14.2	12.3	1.9
349	3	25.7	22.7	3.0
350	4	13.9	12.5	1.4
346	2	13.8	10.6	3.2
343	6	12.2	9.5	2.7
MEAN		15.3	13.1	2.2
S.E.		0.8	0.7	0.2

TABLE 17.

K+ - PREDIALYSIS

ACC#	PT#	NOVA	FLAME	Δ
301	1	5.76	5.95	0.19
302	2	5.50	5.70	0.20
303	3	4.85	5.15	0.70
304	4	4.81	5.00	0.19
305	5	5.67	5.80	0.13
306	6	4.77	5.10	0.33
307	7	4.83	4.95	0.12
308	8	5.36	5.35	0.01
317	9	4.45	4.50	0.05
318	10	4.68	4.70	0.02
319	11	5.29	5.60	0.31
320	12	4.24	4.30	0.06
321	13	4.77	5.00	0.23
322	14	4.80	5.00	0.20
323	15	5.97	6.00	0.03
324	16	4.73	4.80	0.07
325	17	4.25	4.30	0.05
335	7	4.29	4.50	0.31
336	1	5.46	5.80	0.34
337	5	6.09	6.50	0.41
338	8	5.44	5.90	0.46
339	3	6.01	6.30	0.29
340	4	4.50	4.70	0.20
341	2	6.05	6.40	0.35
342	6	5.07	5.40	0.33
MEAN		5.11	5.31	0.22
S.E.		0.10	0.13	0.03

K+ - POSTDIALYSIS

ACC#	PT#	NOVA	FLAME	Δ
309	1	3.56	3.70	0.14
310	2	3.53	3.70	0.17
311	3	3.80	4.00	0.20
312	4	3.69	3.80	0.11
313	5	3.51	3.80	0.29
314	6	3.27	3.60	0.33
315	7	3.66	3.90	0.24
316	8	3.03	3.10	0.07
326	9	3.05	3.10	0.05
327	10	3.42	3.50	0.08
328	11	3.55	3.80	0.25
329	12	2.99	3.00	0.01
330	13	3.59	3.50	0.09
331	14	3.43	3.70	0.27
332	15	3.87	3.90	0.03
333	16	3.35	3.50	0.15
334	17	3.57	3.40	0.17
344	7	3.31	3.50	0.19
347	1	3.58	3.80	0.22
345	5	3.69	4.00	0.31
348	8	3.24	3.40	0.16
349	3	4.04	4.20	0.16
350	4	3.63	3.80	0.17
346	2	3.87	4.10	0.23
343	6	3.57	3.80	0.23
MEAN		3.51	3.66	0.17
S.E.		0.05	0.06	0.02

TABLE 18.

Na+ - PREDIALYSIS

ACC#	PT#	NOVA	FLAME	Δ
301	1	140.6	138.0	2.6
302	2	144.3	142.0	2.3
303	3	142.1	139.0	3.1
304	4	145.0	141.5	3.5
305	5	134.7	132.5	2.2
306	6	143.7	140.5	3.2
307	7	142.8	138.5	4.3
308	8	139.0	137.5	1.5
317	9	143.5	142.0	1.5
318	10	142.5	140.0	2.5
319	11	137.8	133.0	4.8
320	12	134.7	132.0	2.7
321	13	139.4	136.0	3.4
322	14	147.8	144.0	3.8
323	15	134.6	130.0	4.6
324	16	144.0	140.0	4.0
325	17	142.4	136.0	6.4
335	7	141.9	142.0	0.1
336	1	142.2	142.0	0.2
337	5	139.9	140.0	0.1
338	8	139.6	141.0	0.4
339	3	142.2	140.0	2.2
340	4	144.3	142.0	2.1
341	2	143.8	145.0	1.2
342	6	142.7	141.0	1.7
MEAN		141.4	139.0	2.5
S.E.		0.7	0.8	0.2

Na+ - POSTDIALYSIS

ACC#	PT#	NOVA	FLAME	Δ
309	1	142.6	140.0	2.6
310	2	142.6	141.0	1.6
311	3	144.0	138.0	6.0
312	4	144.1	140.0	4.1
313	5	141.6	137.0	4.6
314	6	143.2	139.0	4.2
315	7	141.8	138.0	3.8
316	8	141.9	139.0	3.9
326	9	142.3	139.0	3.3
328	11	142.4	138.0	4.4
329	12	138.5	135.0	3.5
330	13	144.6	138.0	6.6
331	14	144.3	140.0	4.3
333	16	144.3	140.0	4.3
344	7	141.3	138.0	3.3
347	1	144.6	140.0	4.6
345	5	143.4	141.0	4.4
348	8	141.5	138.0	3.5
350	4	145.9	140.0	5.9
346	2	143.4	141.0	2.4
343	6	140.1	138.0	3.1
MEAN		142.8	139.0	4.0
S.E.		0.4	0.3	0.3

TABLE 19.

Ca++ - PREDIALYSIS

ACC#	PT#	NOVA	COLOR	Δ
301	1	1.26	2.45	1.19
302	2	1.17	2.40	1.13
303	3	1.20	2.45	1.25
304	4	1.22	2.40	1.18
305	5	0.99	2.00	1.01
306	6	1.15	2.33	1.18
307	7	1.30	2.43	1.13
308	8	1.08	2.03	0.95
317	9	1.29	2.63	1.34
318	10	1.24	2.28	1.04
319	11	1.14	2.23	1.09
320	12	1.07	2.13	1.06
321	13	1.17	2.20	1.03
322	14	1.24	2.40	1.16
323	15	1.31	2.65	1.34
324	16	1.10	2.18	1.08
325	17	1.16	2.30	1.14
MEAN		1.18	2.32	1.14
S.E.		0.29	0.56	0.02

Ca++ - POSTDIALYSIS

ACC#	PT#	NOVA	COLOR	Δ
309	1	1.35	2.55	1.20
310	2	1.33	2.70	1.37
311	3	1.39	3.05	1.66
312	4	1.31	2.63	1.32
313	5	1.27	2.48	1.21
314	6	1.31	2.55	1.24
315	7	1.35	2.58	1.23
316	8	1.23	2.25	1.02
326	9	1.42	2.68	1.46
327	10	1.28	2.55	1.27
328	11	1.38	2.58	1.20
329	12	1.29	2.35	1.06
330	13	1.36	2.80	1.44
331	14	1.32	2.70	1.38
332	15	1.40	2.70	1.30
333	16	1.27	2.40	1.13
334	17	1.31	2.60	1.29
MEAN		1.33	2.60	1.28
S.E.		0.01	0.04	0.04

TABLE 20.

pH - PREDIALYSIS

ACC#	PT#	NOVA	CORNING	Δ
301	1	7.335	7.320	0.015
302	2	7.354	7.350	0.004
303	3	7.278	7.260	0.018
304	4	7.292	7.296	0.004
305	5	7.291	7.290	0.001
306	6	7.336	7.390	0.054
307	7	7.292	7.316	0.026
308	8	7.420	7.418	0.002
317	9	7.435	7.456	0.021
318	10	7.265	7.258	0.007
319	11	7.326	7.342	0.016
320	12	7.354	7.364	0.020
321	13	7.273	7.263	0.010
322	14	7.312	7.320	0.008
323	15	7.292	7.289	0.003
324	16	7.325	7.334	0.009
325	17	7.310	7.294	0.016
335	7	7.275	7.305	0.030
336	1	7.292	7.334	0.042
337	5	7.292	7.318	0.026
338	8	7.337	7.360	0.023
339	3	7.201	7.199	0.002
340	4	7.257	7.306	0.049
341	2	7.290	7.317	0.027
342	6	7.313	7.365	0.052
MEAN		7.310	7.323	0.019
S.E.		0.010	0.011	0.003

pH - POSTDIALYSIS

ACC#	PT#	NOVA	CORNING	Δ
309	1	7.336	7.326	0.010
310	2	7.392	7.399	0.007
311	3	7.334	7.304	0.020
312	4	7.348	7.352	0.004
313	5	7.292	7.326	0.034
314	6	7.355	7.365	0.010
315	7	7.334	7.337	0.003
16	8	7.392	7.397	0.005
326	9	7.435	7.451	0.016
327	10	7.357	7.370	0.013
328	11	7.330	7.325	0.005
329	12	7.360	7.346	0.014
330	13	7.320	7.324	0.004
331	14	7.417	7.452	0.035
332	15	7.312	7.307	0.005
333	16	7.352	7.350	0.002
334	17	7.340	7.327	0.013
344	7	7.339	7.345	0.006
347	1	7.343	7.335	0.008
345	5	7.299	7.299	0.000
348	8	7.384	7.403	0.019
349	3	7.296	7.263	0.033
350	4	7.304	7.292	0.012
346	2	7.415	7.403	0.012
343	6	7.449	7.473	0.024
MEAN		7.353	7.355	0.013
S.E.		0.009	0.011	0.002

TABLE 21.

COMPARISON OF VENOUS BLOOD VALUES
IN 14 NORMAL CONTROLS

VARIABLE	NOVA	STANDARD	
pH	7.307 ± 0.01	7.315 ± 0.01	P>0.05
PCO2(mmHg)	53.9 ± 1.23	51.8 ± 1.15	P>0.05
PO2(mmHg	27.5 ± 0.96	26.6 ± 1.71	P>0.05
Hct(%)	44 ± 0.80	45 ± 0.80	P>0.05
Hbc(g/dl)	14.7 ± 0.24	15.0 ± 0.27	P>0.05
HCO3 (mmol/l)	27.0 ± 0.35	26.3 ± 0.51	P>0.05
O2Sat(%)	44.6 ± 3.80	45.0 ± 3.9	P>0.05
O2Ct(ml/dl)	9.1 ± 0.80	9.5 ± 0.86	P>0.05
Na+(mmol/l)	144.6 ± 0.51	141.6 ± 0.70	P>0.05
K+(mmol/l)	4.38 ± 0.08	4.41 ± 0.28	P>0.05
Ca++ (mmol/l)	1.39 ± 0.01	2.41 ± 0.02	P<0.05

VALUES ARE MEAN ± STANDARD ERROR

TABLE 22

ALIQUOT NUMBER
all aliquots determined within 11 min.

	1	2	3	4	Mean	Max. Δ from Mean (%)
pH	7.518	7.524	7.514	7.516	7.518	0.08
PCO2 (mmHg)	22.7	22.2	23.0	22.5	22.6	1.77
PO2 (mmHg)	62.1	63.5	66.9	68.2	65.2	4.76
Hct (%)	30	30	31	30	30.25	2.48
Na+ (mM)	147.9	148.2	148.1	148.5	148.2	0.20
K+ (mM)	3.3	3.2	3.3	3.2	3.25	1.54
Ca++ (mM)	1.22	1.19	1.22	1.20	1.21	1.65
Hbc (g/dl)	10.1	10.1	10.2	9.9	10.1	1.98
O2Sat (%)	94.3	94.7	95.3	95.6	95.0	0.74
O2Ct (ml/dl)	13.2	13.3	13.4	13.1	13.25	1.13
HCO3- (mM)	18.6	18.4	18.7	18.3	18.5	1.08

ALIQUOT NUMBER
all aliquots determined within 12 min.

	1	2	3	4	Mean	Max. Δ from Mean (%)
pH	7.573	7.547	7.544	7.550	7.554	0.25
PCO2 (mmHg)	17.1	18.2	17.6	18.3	17.8	3.93
PO2 (mmHg)	60.9	61.0	60.2	61.2	60.8	0.99
Hct (%)	35	36	34	35	35	2.86
Na+ (mM)	150.7	150.9	151.8	151.1	151.1	0.46
K+ (mM)	2.5	2.6	2.5	2.7	2.6	3.85
Ca++ (mM)	0.97	1.03	0.93	1.02	0.99	6.06
Hbc (g/dl)	11.8	12.0	11.4	11.8	11.8	3.39
O2Sat (%)	95.0	94.6	94.4	94.7	94.7	0.32
O2Ct (ml/dl)	15.6	15.7	15.0	15.4	15.4	2.60
HCO3- (mM)	15.9	15.9	15.3	16.1	15.8	3.17

TABLE 22 (con'd)

ALIQUOT NUMBER
all aliquots determined within 18 min.

	1	2	3	4	Mean	Max. Δ from Mean (%)
pH	7.526	7.508	7.514	7.499	7.512	0.19
PCO2 (mmHg)	26.0	25.4	25.6	24.5	25.4	3.54
PO2 (mmHg)	68.2	67.8	65.1	67.2	67.1	2.98
Hct (%)	36	35	35	31	34.25	9.49
Na+ (mM)	149.0	149.7	149.8	150.7	149.8	0.60
K+ (mM)	3.4	3.4	3.5	3.4	3.4	2.94
Ca++ (mM)	1.08	1.06	1.11	0.97	1.06	8.49
Hbc (g/dl)	12.0	11.6	11.6	10.3	11.4	9.65
O2Sat (%)	95.6	95.3	94.8	95.1	95.2	0.63
O2Ct (ml/dl)	15.9	15.3	15.3	13.6	15.0	9.33
HCO3- (mM)	21.6	20.3	20.7	19.2	20.5	6.34

ALIQUOT NUMBER
all aliquots determined within 17 min.

	1	2	3	4	Mean	Max. Δ from Mean (%)
pH	7.446	7.441	7.445	7.453	7.446	0.09
PCO2 (mmHg)	26.4	25.3	26.5	25.5	25.9	2.32
PO2 (mmHg)	104.7	108.3	107.3	108.7	107.3	2.42
Hct (%)	35	33	34	33	33.75	3.70
Na+ (mM)	151.6	151.7	151.9	151.7	151.7	0.13
K+ (mM)	3.4	3.3	3.5	3.4	3.4	2.94
Ca++ (mM)	1.16	1.08	1.15	1.09	1.12	3.57
Hbc (g/dl)	11.7	11.1	11.3	11.1	11.3	3.54
O2Sat (%)	98.4	98.5	98.5	98.6	98.5	0.10
O2Ct (ml/dl)	15.9	15.2	15.5	15.2	15.5	2.58
HCO3- (mM)	18.3	17.3	18.3	17.9	18.0	3.89

TABLE 22 (con'd)

	ALIQUOT NUMBER all aliquots determined within 16 min. 1	2	3	4	Mean	Max. Δ from Mean (%)
pH	7.473	7.491	7.478	7.481	7.481	0.13
PCO2 (mmHg)	23.8	23.4	22.3	21.7	22.8	4.82
PO2 (mmHg)	80.5	80.3	79.9	82.2	80.7	1.86
Hct (%)	29	29	29	28	28.75	0.87
Na+ (mM)	148.6	148.5	148.7	149.1	148.7	0.27
K+ (mM)	3.94	3.91	3.96	3.82	3.91	2.30
Ca++ (mM)	1.34	1.34	1.35	1.29	1.33	3.01
Hbc (g/dl)	9.8	9.6	9.6	9.3	9.575	2.35
O2Sat (%)	96.9	97.0	96.9	97.2	97.0	0.21
O2Ct (ml/dl)	13.1	13.0	12.9	12.5	12.9	3.10
HCO3- (mM)	17.5	17.9	16.6	16.3	17.1	4.68

	ALIQUOT NUMBER all aliquots determined within 16 min. 1	2	3	4	Mean	Max. Δ from Mean (%)
pH	7.391	7.390	7.382	7.382	7.386	0.068
PCO2 (mmHg)	26.1	25.7	26.4	26.5	26.2	1.91
PO2 (mmHg)	114.7	109.7	105.5	107.7	109.4	4.84
Hct (%)	39	38	37	38	38	2.63
Na+ (mM)	148.1	148.9	149.1	148.8	148.7	0.40
K+ (mM)	3.37	3.17	3.23	3.26	3.26	3.37
Ca++ (mM)	1.24	1.19	1.23	1.26	1.23	3.25
Hbc (g/dl)	13.0	12.5	12.5	12.6	12.7	2.36
O2Sat (%)	98.6	98.4	98.1	98.2	98.3	0.31
O2Ct (ml/dl)	17.7	17.1	17.0	17.2	17.3	2.31
HCO3- (mM)	15.9	15.6	15.7	15.8	15.75	0.95

V. CONCLUSIONS

The important conclusions which result from the current work are as follows:

(1) Assessment of chemical data variables in blood, especially venous blood, may be useful in evaluating conditions of low cardiac output and low tissue perfusion. Relevant chemical data variables include the following:

PO_2

Hematocrit

Oxygen content

PCO_2

pH

Bicarbonate

Glucose

Lactate

Potassium Ion

(2) Although requiring more invasive sampling techniques, analysis of blood gases in arterial blood would assist in distinguishing blood chemistry changes resulting from impairments in pulmonary gas exchange in those resulting from low tissue perfusion.

(3) Technology is currently available quantitation of important blood chemistry data variables. For ions and certain other chemical components, existing technology makes use of ion-selective electrode technology. Optimally, the instrumentation used for analysis of blood chemistry, including blood gases and other chemical components, should have the capacity to quantitate required data variables in a single small sample of whole blood.

(4) A prototype off-the-shelf instrument is currently available for quantitation of many of the important required data variables. This instrument is the Stat Profile-1 Analyzer manufactured by NOVA Biomedical Company.

(5) An in-depth evaluation of the NOVA Stat Profile-1 in comparison with accepted Gold Standard techniques reveals that the instrument provides reliable quantitative information on the following important chemical data variables in venous blood:

PO_2

Hematocrit

Oxygen Content

PCO_2

pH

Bicarbonate Concentration

Potassium Ion Concentration

(6) Experience with the NOVA Stat Profile-1 reveals that the instrument is simple in its operation and maintenance and requires minimal training by the user.

VI. RECOMMENDATIONS

Based on the work performed under contract NAS 9-17594, the following recommendations for future action are made:

(1) The NOVA Stat Profile-1 Analyzer should be seriously considered for use in the Space Station Health Maintenance Facility. In this regard, it should be noted that NOVA Biomedical Company manufactures electrodes for quantitation of chloride ion concentration and glucose concentration. The reliability of these electrodes was not assessed in the current work evaluating the Stat Profile-1 Analyzer. However, the electrodes utilize accepted technology as described in Section IIB of this report and it would be, therefore, expected that results utilizing these electrodes would be equivalent in reliability to those actually evaluated in the current work. Since glucose concentration would be an especially valuable data variable, not only in evaluating low blood flow states but also in evaluating the nutritional state of the Space Station worker, it is highly recommended that the glucose electrode be tested by practical means such as employed in the current work. If its performance is found to be satisfactory, its use should be seriously considered as an integral part of the Stat Profile-1 instrument.

(2) Certain repackaging of the instrument may be required to facilitate its use in the Health Maintenance Facility. The printer used for producing hard copy of information displayed on the CRT screen may not be required and could be deleted from the instrument as used in the HMF. The CRT and microcomputer with associated circuitry may be incorporated into the central HMF computer and data acquisition system and, thereby, deleted from the Stat Profile-1 package itself. It is predicted that these deletions from the instrument would conserve considerable space and weight. In addition, the power requirement for the instrument, as now designed, is a 60 cycle, 120 volt alternating current which is converted to a direct current by an internal transformer and associated circuitry. With the availability of a direct current power supply, the internal transformer system may be deleted. It is recommended that further communication with the manufacturer, NOVA Biomedical, be established in order to facilitate redesign of the instrument along the above lines. Consultation with the manufacturer may also result in further repackaging of the instrument in the interest of space and weight conservation.

(3) The NOVA Stat Profile-1 Analyzer uses an active pump mechanism for moving reagents, waste, and sample fluids. Since this mechanism of fluid movement is not gravity dependent, no special modifications in this mechanism are necessary. In this regard, it should also be noted that within the reagent pack of the instrument, reagent fluids are contained in rigid plastic,

vented containers. Since the HMF will be pressurized, it is not foreseen that a change in the reagent pack system will be required.

(4) The NOVA Stat Profile-1 has the capacity for quantitation not only of potassium ion as listed above, but also for other ions including sodium, calcium, and chloride. In the current work, the reliability of the instrument in determination of potassium ion, sodium ion, and calcium ion concentrations in blood were assessed. As pointed out above, changes in the value of venous blood potassium ion concentration may be especially useful if evaluating low tissue perfusion states. Changes in the concentrations of blood sodium and calcium are less useful in evaluation of low blood flow states but may be valuable data variables for assessment of other important health maintenance problems relevant to human life in a weightless environment. It is recommended that consideration be given to future studies regarding the importance of sodium and calcium quantitation in the Space Station. The rationale of this recommendation is as follows:

Weightlessness is known to result in a redistribution of blood volume, leading to an increase in the central blood volume. An increase in central blood volume is know to result in stimulation of certain neural receptors located in central blood vascular chambers. Such receptors are located especially in the vena cavae and right atrium as well as in pulmonary vessels. Stimulation of these receptors by mechanical stretch elicits certain cardiovascular reflexes which result in an increase in salt and water excretion by the kidneys. Likewise, stretch of the atria is known to cause formation and secretion of the hormone Atrial Natriuretic Factor, and this hormone strongly promotes sodium and water excretion by the kidneys. Because of these factors, it may be predicted that without an appropriate balance by increased sodium intake, body fluid sodium concentration would show a marked reduction in a weightless environment. For this reason, a constant assessment of sodium ion concentration in the body fluids would be important in the Manned Space Station.

A weightless environment will also lead to reduced stress of the body's skeletal system. Reduced stress on bones is felt to result in an impairment in the balance between bone synthesis and degradation, leading to a reduction in bone mass. A study designed to assess bone calcium turnover by quantitation of blood and/or urine calcium concentration may be extremely useful in determining the effects of long-term weightlessness on skeletal structure of the body.

(5) The NOVA Stat Profile-1 used in the present work did not have the capacity for quantitation of blood lactate concentration. As pointed out in Section IIA, venous blood lactate should prove to be a valuable chemical data variable in the assessment of low tissue perfusion states. As pointed out in

Section IIB above, electrode technology is currently available for quantitation of lactate concentrations in fluids. Future efforts should be directed towards incorporation of a lactate electrode into a blood chemistry analyzer such as the NOVA Stat Profile-1.

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VIII. INDEX

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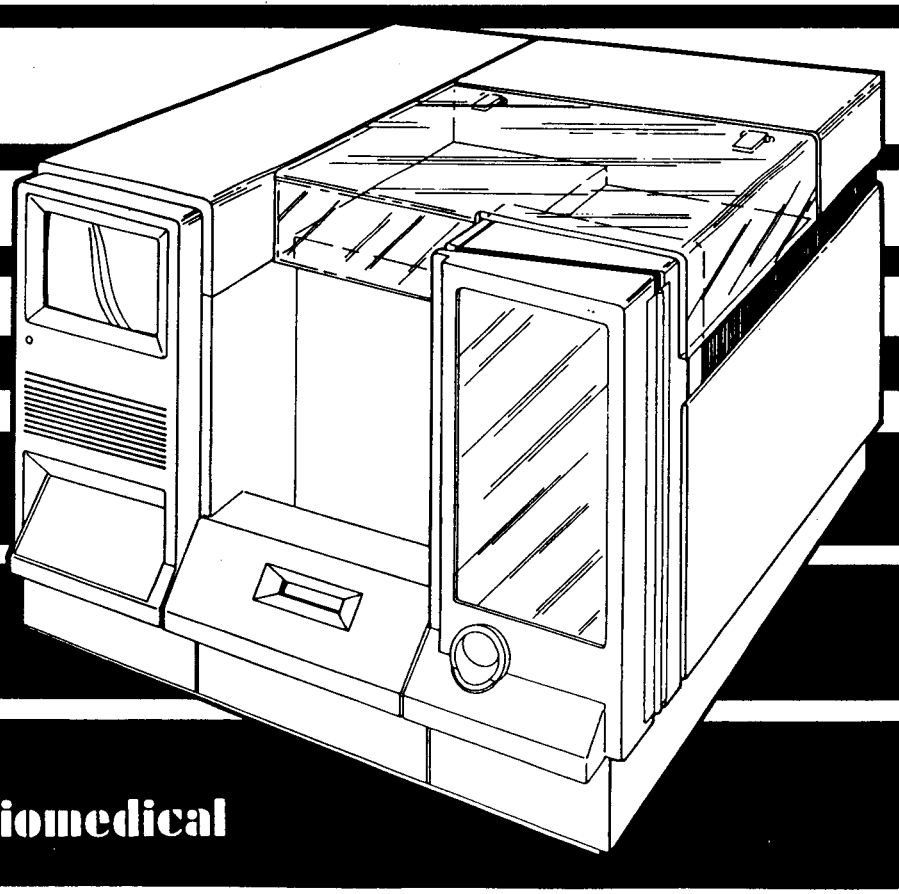
STAT profile

Instruction Manual



NOVA biomedical

NOTE: Use ONLY solutions provided by NOVA Biomedical with the Stat Profile 1. These solutions are formulated and manufactured specifically for use with NOVA's electrode technology. Solutions from any other source, though they may appear appropriate for use, can contain agents (preservatives, wetting agents, buffers, etc.) that interfere with Stat Profile 1 electrode performance. Use of such solutions will void the Stat Profile 1 electrode warranty.

TOLL FREE
TECHNICAL ASSISTANCE

If you have questions regarding this instrument or require service assistance, call toll free
1-800-545-NOVA

In Massachusetts call
(617) 894-0800

Table of Contents

List of Tables

Table of Figures

1 General Information

This manual provides all necessary instructions for the routine operation and maintenance of the NOVA Stat Profile 1. Please read this manual carefully. It has been prepared to assist you in attaining optimum performance from the NOVA Stat Profile 1 analyzer.

This section introduces the Stat Profile 1, covering tests performed, procedural limitations, and giving an overview of the components, operation, and system program.

1.1 Tests Performed and Procedural Limitations

The NOVA Stat Profile 1 analyzer combines blood gas and related stat tests of serum, plasma, whole blood, and expired gas for in vitro diagnostic use.

Samples are analyzed for

- pH
- PCO_2
- PO_2
- Sodium (Na)
- Potassium (K)
- Ionized Calcium (Ca^{++})
- Hematocrit (Hct)

From the directly measured results, the calculated results are:

- Oxygen Saturation level (O_2Sat)
- Base Excess of the Blood (BE-B)
- Base Excess of Extracellular Fluid (BE-ECF)
- Bicarbonate level (HCO_3^-)
- Standard Bicarbonate Concentration (SBC)
- Total Carbon Dioxide (TCO_2)
- Oxygen content (O_2Ct)
- Normalized Calcium (nCa^{++})
- Hemoglobin (Hb_c)

Acceptable samples for the NOVA Stat Profile 1 are arterial, venous, or capillary whole blood, plasma, or serum samples collected anaerobically (or aerobically for sodium and potassium) or expired gas samples.

When a flashing result is displayed on the results screen and printed with a question mark, this is an indication that a minor error has occurred during the analysis. Refer to the displayed error code to interpret whether to accept or reject the result.

Throughout this manual, NOTE: indicates especially important information and CAUTION: indicates information that is critical to avoid instrument damage or incorrect results.

1.2 Component Overview

The NOVA Stat Profile 1 components are shown in Figure 1.1. These components are described in the following sections.

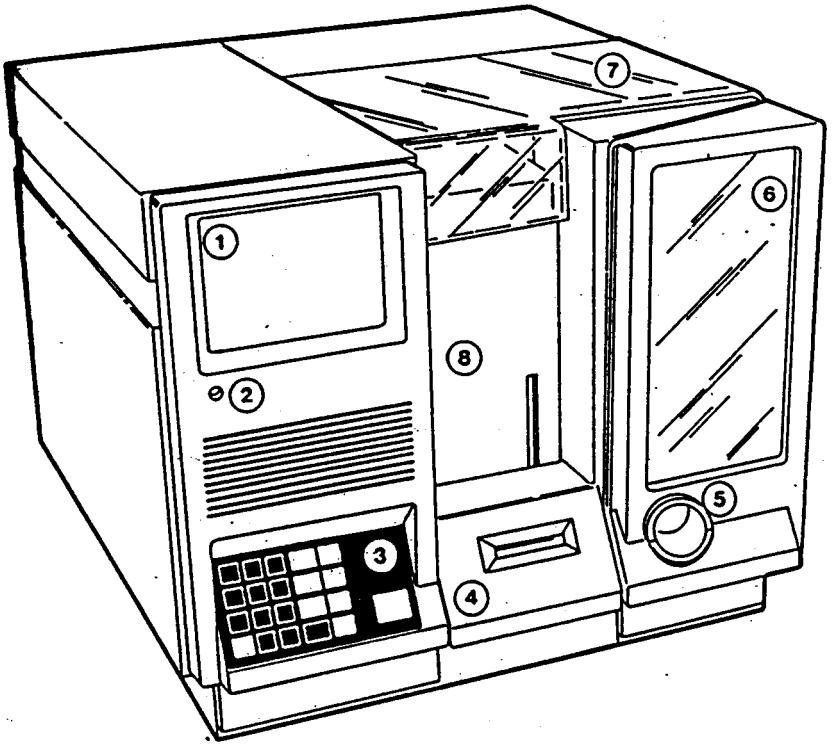


Figure 1.1 NOVA Stat Profile 1 Components

1. CRT Display
2. Instrument Status Light
3. Keypad
4. Printer
5. Septum Assembly Inlet Port
6. Analytical Compartment
7. Fluids Deck
8. Reagent Pack

1.2.1 Stat Profile 1 Keypad and Functions

The instrument is controlled by a keypad as shown in Figure 1.2, with keys explained in Table 1.1.

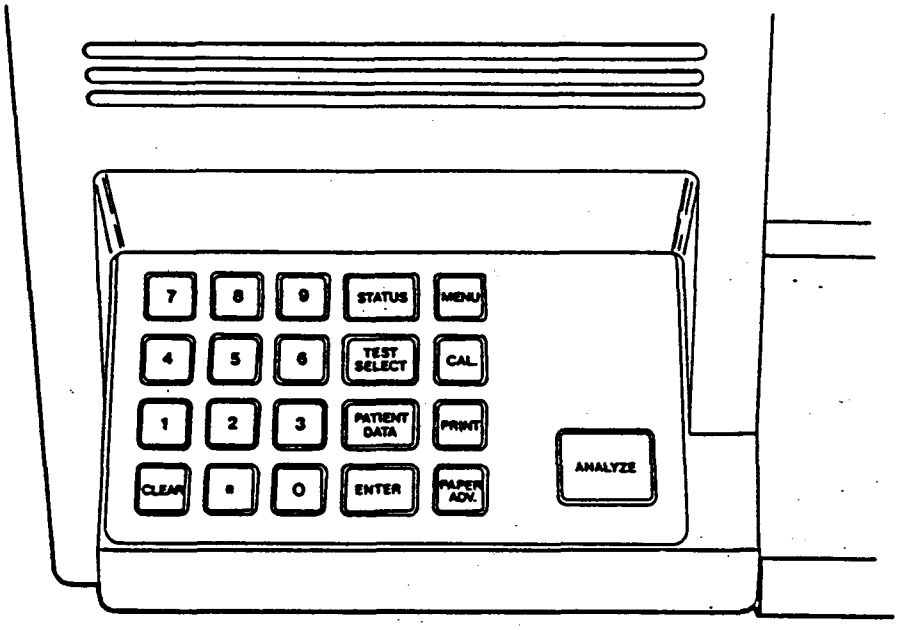


Figure 1.2 Keypad

Table 1.1 Key Functions

Key	Function
ANALYZE	Starts an analysis using the currently selected test mode. This key is inoperative if the system is busy with another sequence.
CAL	Starts a full two-point calibration. This key is inoperative if the system is busy with another sequence.
TEST SELECT	Selects or changes the current analysis mode, as seen in the READY (NOT READY) FOR ANALYSIS screen, to any of the 4 following modes: 1. Blood Gas + Electrolytes 2. Expired Gas 3. Blood Gas Only 4. Electrolytes Only The TEST SELECT key changes the analysis mode for 1 patient sample only. At the end of an analysis, the Default Analysis Mode will be restored (Section 2.2.1). The key is only operational from the READY (NOT READY) FOR ANALYSIS screen, when no calibration or analysis is in progress.

PATIENT DATA

1. During an analysis, enables you to enter the accession number, patient I.D. number, temperature, hemoglobin, sample type, time drawn, and percent inspired oxygen values.

2. When an analysis is not being performed, recalls results from the last analysis.

3. When pressed twice from the READY FOR ANALYSIS screen, allows you to enter alternate patient data, recalculating the previous results.

The Patient Data screen cannot be accessed if a Menu or Status screen is currently being displayed on the CRT.

STATUS

Causes the Sensor Status screen to be displayed. This is the first of four Status screens; you can cycle through them using the ENTER or STATUS keys.

MENU

Causes the Main Menu to be displayed. This allows you to access the four support sections of the software. As you become more experienced, you can bypass the MENU key (and the Main Menu) by pressing the digit key (1 - 4) corresponding to the four support sections.

PRINT

Causes a manual printout of the contents of the currently displayed screen. If the printer is printing, the PRINT key will be ignored.

PAPER ADV

Causes a one-line paper advance. If the printer is printing, the PAPER ADV key will be ignored.

ENTER

1. To enter numbers on data entry screens.
2. To skip an entry on a data entry screen. ENTER advances the cursor to the next entry on the data entry screen.
3. To step to the next screen in a sequence of screens.
4. To initiate an action or cycle, such as a mini-cal or a gas/fluid prime, or to abort a sequence.
5. To increase the Analog Multiplexer Channel Number on the System Test screens.

CLEAR

1. To delete numbers on data entry screens.
2. To exit from a screen.
3. To abort a sequence in progress.

. (Decimal Pt.)

1. As a decimal point when entering numbers.
2. As a separator in the Patient I.D., accession number, and time drawn (instead of a hyphen, slash, space, or colon).
3. To decrease the Analog Multiplexer Channel Number in the System Test screen.
4. To recall "blanked" screen (see Section 1.2).

0-9 (Digits)

1. Numeric entry.
2. Menu Selection.

1.2.2 CRT Display

The CRT Display displays screens of information on system functions, how to access system functions, and patient results. If the instrument is idle for more than 30 minutes, the computer will automatically "blank" the CRT to minimize wear to the unit. In this situation, pressing the . key will recall the screen that was "blanked."

NOTE: Pressing keys other than . will recall the previous screen also, but may activate functions on these screens.

1.2.3 Instrument Status Light

The Instrument Status Light enables you to monitor instrument readiness without having to access the Status screens, or without having to recall a "blanked" display. The light is:

- Green when ready for an analysis
- Flashing Green when either:
  1. There is less than 10 minutes until an Auto-Cal (automatic calibration) or,
  2. More than 2 hours has passed since the last calibration and samples are being analyzed at a rate of greater than 1 every 5 minutes
- Red when the system is uncalibrated or not temperature equilibrated (the NOT READY screen is displayed)
- Flashing Red when the instrument is in Program Fail
- Off when the instrument is in reset or is unplugged

An analysis can be performed when the light is green or flashing green. When the light is red, the results, if any, may not be valid. If the light is flashing red, press CLEAR to reset the instrument and possibly correct the problem; in this situation, all set-up parameters are lost. If the light continues to flash red, contact NOVA Biomedical Technical Service.

1.2.4 Analytical Compartment

The Analytical Compartment contains the electrodes and the components of the flow path, which are the Sampler Probe, Septum Assembly, Sample Preheater, Flow Cell and tubing harnesses to bring the samples and standards in contact with the electrodes. The Barometric Pressure Module, Gas Humidifier Wells, Reference Electrode, Reagent Preheater, and temperature regulation devices are also contained in this compartment. The compartment is thermostatted to 37° C.

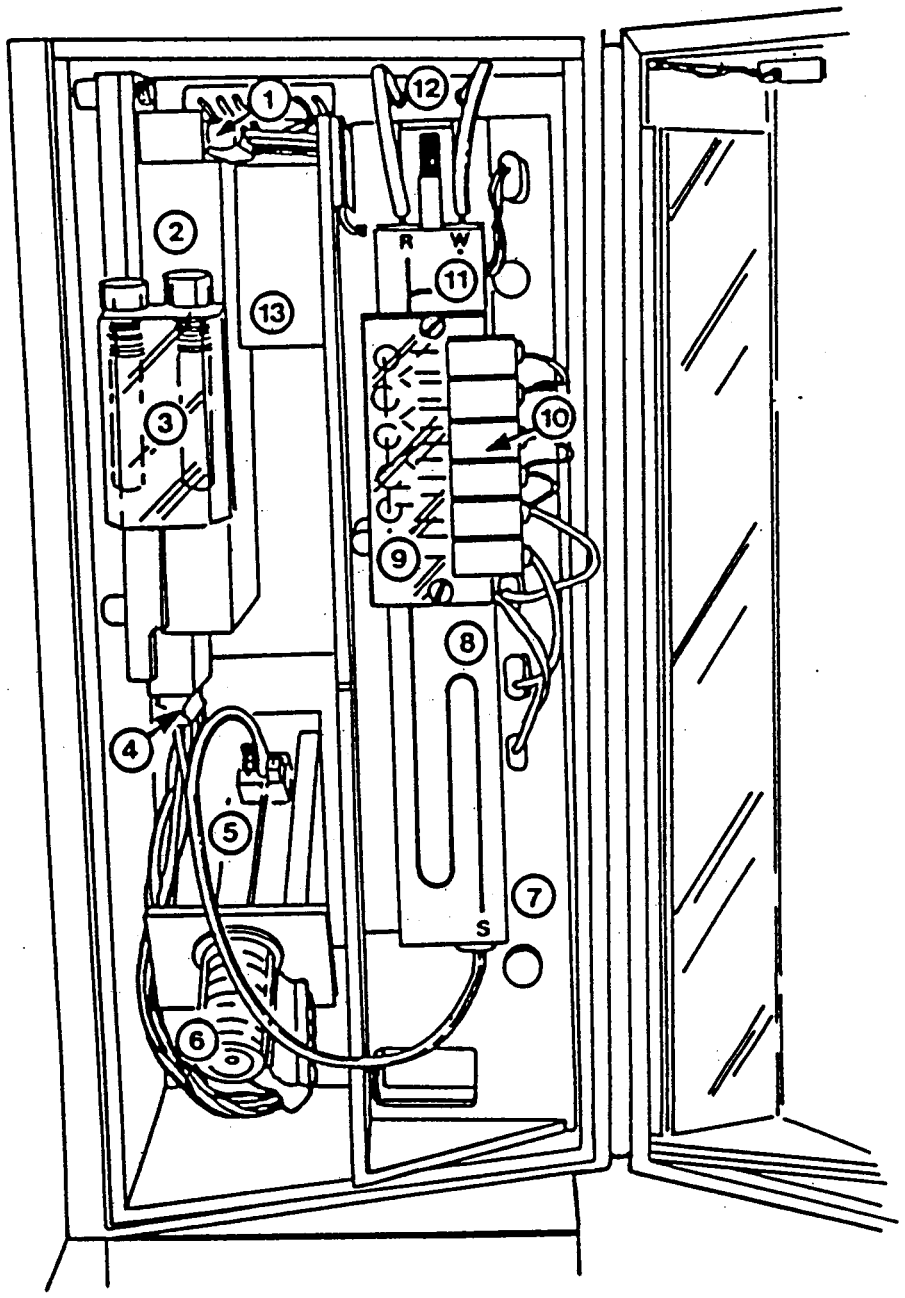


Figure 1.3 Analytical Compartment

1. Reagent Harness
2. Reagent Preheater
3. Gas Humidifier Wells
4. Septum Harness
5. Sample Probe
6. Septum Assembly
7. Electrode Rack Assembly
8. Sample Preheater
9. Flow Cell
10. Electrodes
11. Reference Electrode
12. W/R Harness
13. Barometric Pressure Module

1.2.4.1 Reagent Preheater

The Reagent Preheater preheats the Reagent Pack fluids and the gases to 37° C.

1.2.4.2 Gas Humidifier Wells

The Humidifier Wells contain deionized water which the gases are bubbled through for humidification and visual confirmation of gas flow.

1.2.4.3 Sampler Assembly

The Sampler Assembly consists of the Sampler Probe, Septum Assembly, Sampler Housing, and Stepping Motor. The Sampler Probe moves through the Sampler Housing and Septum Assembly by action of the stepping motor. Inside the Septum Assembly, aspiration of reagents and gases occurs by moving the probe to the appropriate compartments within the Septum Assembly. Outside the Septum assembly, the Sampler Probe allows presentation of syringes, capillary tubes, sample cups, vacuum tubes or expired air samples.

The Septum Assembly is comprised of 6 septa-walled compartments, into which flow the appropriate gas or standard solutions for Sampler Probe access.

1.2.4.4 Sample Preheater

The Sample Preheater preheats samples and reagents to 37°C. In addition, it contains the Hematocrit Impedance Electrode and two air detectors. A backplate extending from the Sample Preheater serves to hold the Flow Cell and the Reference electrode.

1.2.4.5 Flow Cell

The Flow Cell houses the electrodes in a clear block with a prism surface to enable visual detection of clots and air bubbles.

1.2.4.6 Electrodes

The electrodes housed in the Flow Cell form the core of the analytical section of the Stat Profile 1. All electrodes are of flow-by design to minimize sample size. The methodology of each electrode is as follows in Table 1.2.

Table 1.2 Stat Profile 1 Electrode Methodologies

Electrode	Methodology
Sodium	Sodium ion-selective electrode glass
Potassium	Valinomycin ion exchanger membrane
Calcium	Neutral Carrier membrane electrode
pH	Hydrogen ion selective electrode glass
PCO_2	Severinghaus-type electrode
PO_2	Polarographic Clark-type electrode
Hct	Impedance Electrode

The electrodes clip into the Flow Cell (the Hct electrode is part of the Sample Preheater), and the cables plug into the Electrode Rack Assembly. The voltages read by the Na, K, Ca^{++}, and pH electrodes are related to a reference voltage from the reference electrode. Voltages from the PCO_2 and PO_2 electrodes are related to their own internal reference electrodes.

1.2.4.7 Reference Electrode

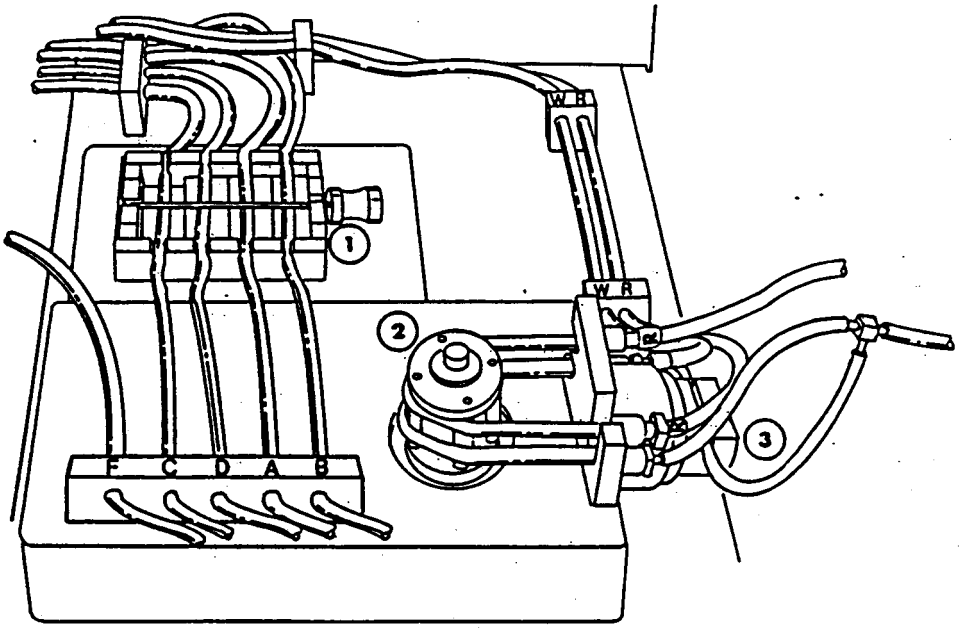
The Reference Electrode is mounted on the Sample Preheater above the Flow Cell. It is a solid-state electrode continuously supplied with reference solution to provide the reference, base-line voltage necessary for relative comparisons of known standard voltages to unknown sample voltages. The exit port for the flow path is located on this electrode.

1.2.4.8 Barometric Pressure Module

The Barometric Pressure Module, located on the left side of the Electrode Rack Assembly, contains a barometer which continuously monitors the barometric pressure. This barometer can be calibrated against an external barometer if desired (Section 3.2.3).

1.2.5 Reagent Flow Controllers

The Reagent Flow Controllers are located on the Fluids Deck under the plexiglass cover as shown in Figure 1.4. The controllers are the Pump, Pinch Valve, and Pump Bypass Valve. These components are described in the following sections.



1. Pinch Valve
2. Pump
3. Pump Bypass Valve

Figure 1.4 Reagent Flow Controllers

1.2.5.1 Pinch Valve

The Pinch Valve contains four tubing pinch stations which are controlled by a motor driven cam. The valve regulates the flow of standards A, B, C, and D from the Reagent Pack. When the valve position is closed, the valve pressure plate is extended against the valve pinch bar and the tube is pinched closed. When the valve position is open, the valve pressure plate is retracted from the valve pinch bar and the tubing is open, allowing reagents to flow.

1.2.5.2 Pump

The pump uses peristaltic action to draw the fluids through the tubing and the flow path. The stepping motor, which drives the pump, moves at low, medium low, medium high, and high speeds. The pump roller assembly contacts the waste line to draw the standards or samples through the W line and reference solution from the Reagent Pack through the R line into the Reference electrode.

1.2.5.3 Pump Bypass Valve

The Pump Bypass Valve contains a pinch valve which allows gas to bypass the pump (gas cannot flow by peristaltic action) and flow through a bypass tubing segment in the W/R harness.

1.2.6 Printer

The printing mechanism on the sampler/printer uses a heat sensitive paper and a 100 dot thermal printhead. The paper is driven past the printhead by a stepping motor. The actual printing of data or information is done by energizing the proper sequence of dots at the proper place on the paper.

1.3 Operation Overview

The Stat Profile 1 is an automatic, microcomputer-based system for analyzing samples for Blood Gas, Electrolytes, and Hematocrit. Access to the system is through the keypad, allowing entry of data and instructions in response to system information displayed on the CRT.

After the instrument is set up and calibrated, the CRT displays the READY FOR ANALYSIS screen signifying that the instrument is ready to begin analysis of samples. The operator presses ANALYZE to extend the probe, presents the sample, then presses ANALYZE again to begin the analysis cycle. After the sample is moved through the flow path to the electrodes, the electrode millivolt values are measured and error messages generated if any problems are detected. Patient data is entered by the operator, calculations for measured results are performed, and these results are in turn used for computing the calculated results.

A two-point calibration establishes the electrode slopes that sample calculations are based on. The instrument performs a two-point calibration every 2 hours. A one-point calibration is performed after every sample in the single throughput mode. In the normal throughput mode, a one-point calibration is performed every 30 minutes as long as samples are analyzed at a rate of at least one per 15 minutes; if over 15 minutes elapses without a sample analysis, a one-point calibration will automatically be performed after the next sample. Patient results are calculated using the millivolt difference between the one-point calibration standard and the patient sample together with the electrode slope from the last two-point calibration. The one-point calibration is also used to check for unacceptable electrode drift (electrode drift is defined as a small change in electrode signal over time, the slope remaining constant). After the one-point calibration cycle, measured and calculated results are displayed on the CRT and printed out.

The following in-depth description of the two-point calibration can also serve as an example for what happens during a one-point calibration and sample cycle. Refer to Figure 1.5 throughout this description.

After calibration is initiated, the Pump Bypass Valve opens and the probe tip moves to the gas standards position in the Septum Assembly. An internal gas valve allows Gas A into the system. The gas is humidified before flowing into the flow path where the PCO_2 and PO_2 electrodes take the millivolt readings. This sequence is repeated for gas B, establishing the second of the two calibration points for the PCO_2 and PO_2 electrodes. The gas is then purged out of the system and the Pump Bypass Valve closes.

The Pinch Valve opens line B from the Reagent Pack. The Sampler Probe tip moves to the Standard B position in the Septum Assembly, the pump turns, Standard B is aspirated through the Sample Preheater, and the Air Detectors check for proper reagent flow. During aspiration the pump simultaneously pumps Reference Solution into the Reference Electrode. The pH and Hematocrit electrode millivolt readings are taken.

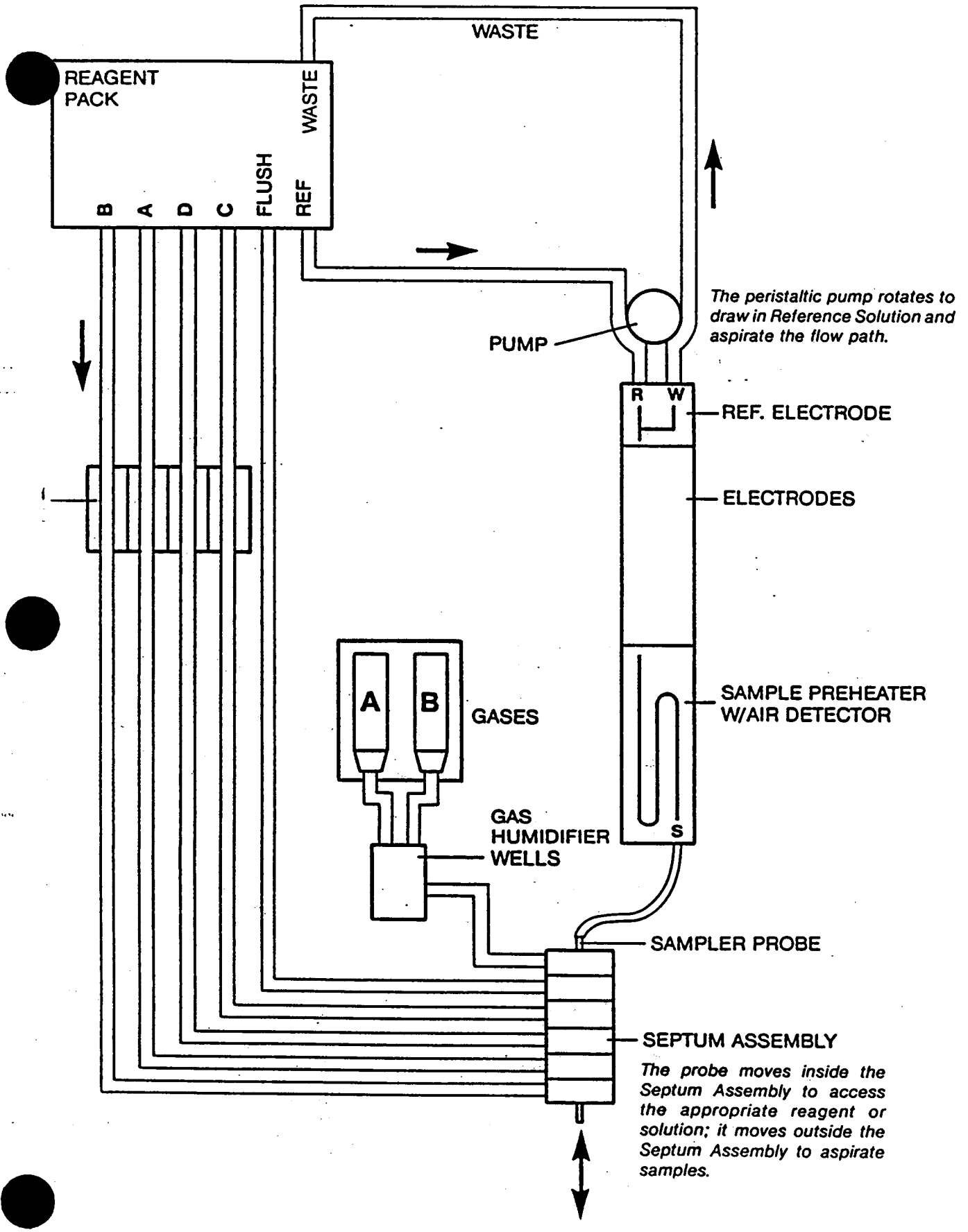


Figure 1.5 Fluidic Diagram

In a similar fashion, this sequence is repeated for Standard A, establishing the second of the two calibration points for the pH electrode (the second point for the Hematocrit electrode is taken when Standard C is read). Finally, the sequence is performed for the Na, K, and Ca^{++} electrodes, using Standard D for the first calibration point then Standard C for the second calibration point.

A barometer provides continuous pressure readings which are used in the calculation of blood gas results. The analytical compartment is controlled at 37.0° C. An idle sequence is performed if the instrument is idle for more than 30 minutes. This sequence maintains the electrodes in the appropriate, refreshed medium -- flush solution for the Na, K, Ca^{++}, and pH electrodes and Gas A for the PCO_2 and PO_2 electrodes.

1.4 Program Overview

The operator controls the instrument by accessing the desired program function. This occurs through use of the membrane keypad in response to the CRT display. The program is accessed to:

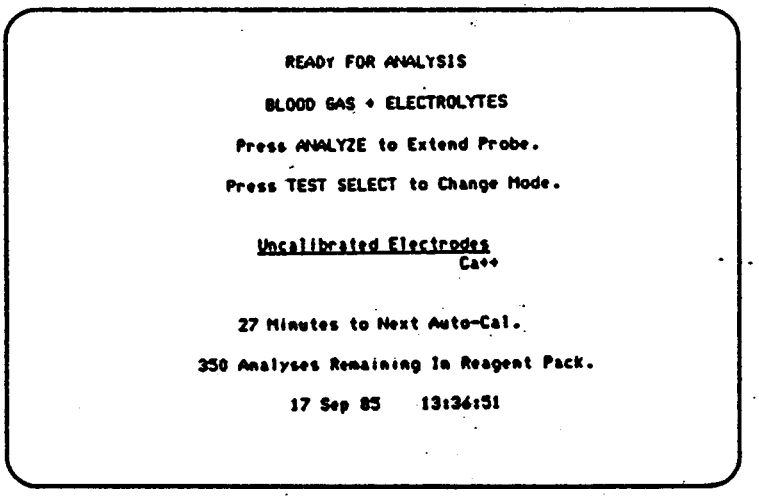
- Analyze a Sample
- Calibrate the Instrument
- Perform Maintenance
- Set Instrument and Test parameters
- Diagnose a Problem

The instrument CRT screens are either information on a function that is being or has been performed, general lists of function options (known as menus), information to enable changing system or test parameters, or patient results. An explanation of how these display screens fit together and the number or function key to press to move through the sequence of functions is shown on the screen map on the quick reference card.

All instrument screens contain information on how to move to the next relevant screen and how to exit the screen. The screen that most sequences of screens must begin from is the READY FOR ANALYSIS screen. An introduction to this screen and the Status and Main Menu screens is as follows.

1.4.1 READY (NOT READY) FOR ANALYSIS

The READY FOR ANALYSIS screen tells whether the instrument is ready to perform an analysis within the parameters selected by TEST SELECT. When the NOT READY version of this screen is displayed (see Section 2.1.1), initialize the program per Section 2.1.1.



READY FOR ANALYSIS

The following information is displayed:

- Analysis mode
- Initial set up steps necessary (when instrument is not ready)
- When ready for an analysis, information on how to begin the analysis
- Uncalibrated electrodes
- Time to next Auto-Cal
- Number of analyses remaining in the Reagent Pack
- Date and time

1.4.2 STATUS

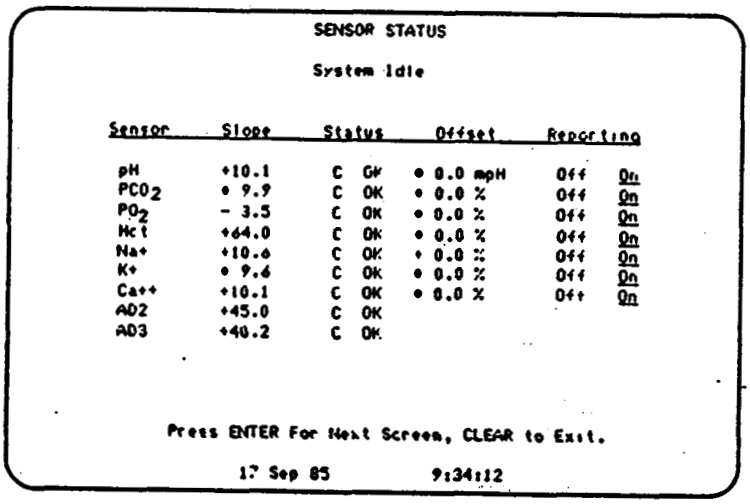
The 4 Status screens are as follows:

- Sensor Status
- Sequence Errors
- System Errors
- System Status

These screens are accessed in a cyclic fashion; repeatedly pressing ENTER or STATUS will cycle you through the screens. The screens can be accessed at any time during an analysis, calibration or idle sequence. Press CLEAR to leave any Status screen and recall the screen that preceded access of the Status screen.

1.4.2.1 SENSOR STATUS

The Sensor Status screen is the first screen displayed when STATUS is pressed.



SENSOR STATUS

This screen provides the following information:

- Sequence in Progress
- Time to Completion of Sequence
- Slopes of each electrode and air detector delta millivolts
- Status of each electrode and air detector - minor or major error occurance for last calibration or analysis cycle

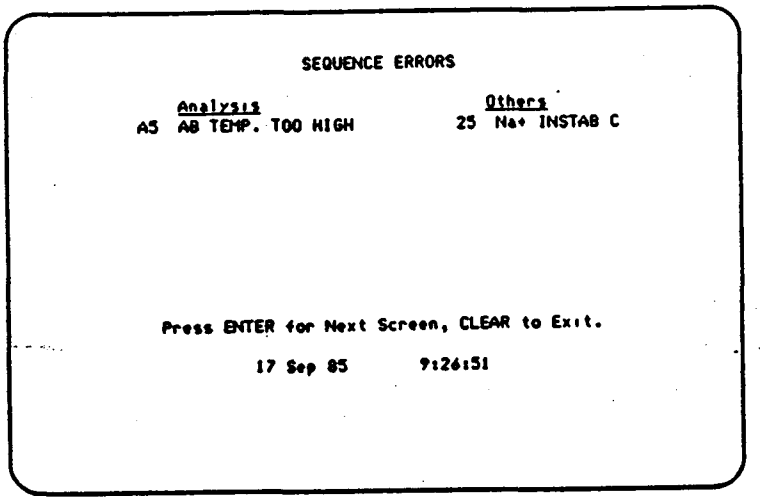
  C or UC - Indicates whether an electrode is calibrated or uncalibrated

  E or OK - Indicates whether an error has occured on that electrode (major or minor, calibration or analysis)

- Reporting status of electrode - if results are being reported for the particular parameter
- Electrode offsets

1.4.2.2 SEQUENCE ERRORS

The Sequence Error screen is accessed from the Sensor Status screen by pressing ENTER.

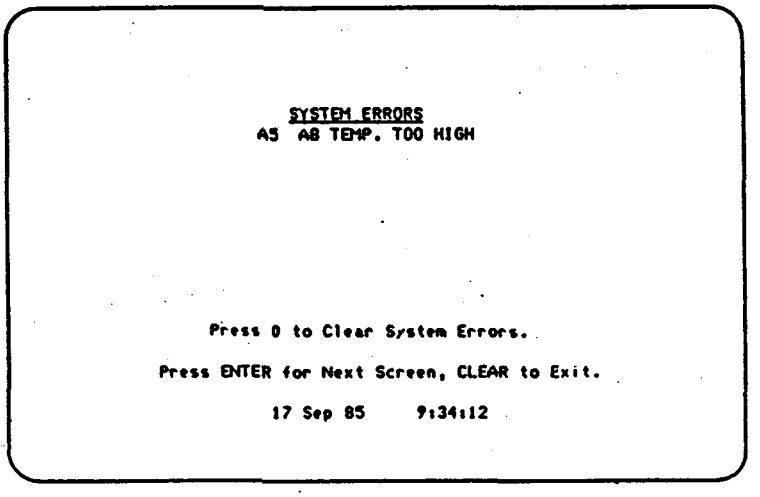


SEQUENCE ERRORS

This screen lists sequence error codes (which are mainly electrode or fluidic in nature) from the last analysis (labeled Analysis) and from calibrations and other operations (labeled Other). The screen is updated with each calibration and analysis. Refer to Section 6.1 for a discussion of troubleshooting with this screen.

1.4.2.3 SYSTEM ERRORS

The System Errors screen is accessed from the Sequence Error screen by pressing ENTER.

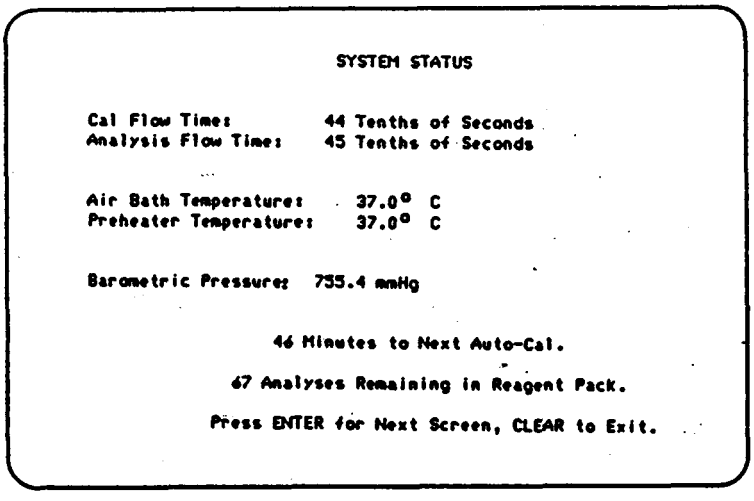


SYSTEM ERRORS

System error codes are hardware or software related. These codes can occur at any time--during calibration, analysis, or during an idle sequence. These error codes do not clear automatically. Refer to Section 6.1 for a discussion of troubleshooting with this screen.

1.4.2.4 SYSTEM STATUS

The System Status screen is accessed from the System Error screen by pressing ENTER.



SYSTEM STATUS

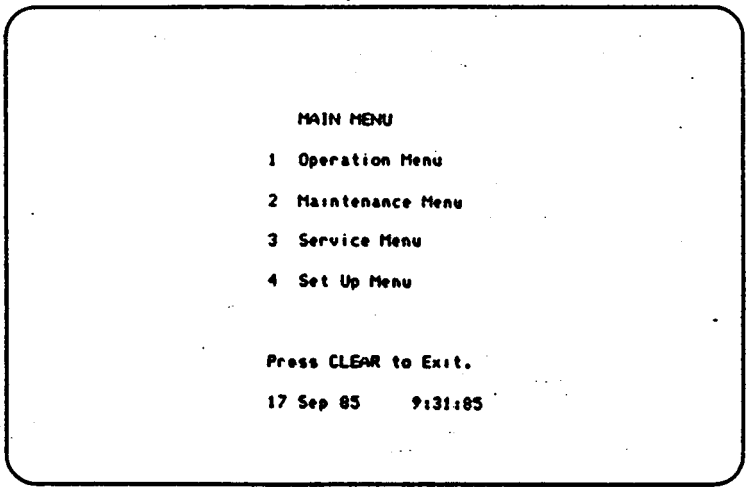
This screen provides the following information:

- Calibration flow time
- Analysis flow time
- Air bath temperature
- Preheater temperature
- Barometric pressure
- Time until next Auto-Cal
- Number of analyses remaining in Reagent Pack

Pressing ENTER again returns you to the Sensor Status screen and completes the cycle.

1.4.3 MAIN MENU

The Main Menu is accessed from the READY (NOT READY) FOR ANALYSIS screen by pressing MENU. The supporting functions of the instrument are broken down into four catagories at the MAIN MENU screen.



MAIN MENU

By pressing 1, 2, 3, or 4, you select the Operation, Maintenance, Service, or Set-up menu respectively. Each of these menus displays a list of numbered functions for keypad selection. Each menu and their functions are explained in the appropriate section of this manual.

The Main Menu (and the MENU key) may be bypassed by pressing the appropriate digit (1 = Operation, 2 = Maintenance, etc.) from the READY FOR ANALYSIS screen.

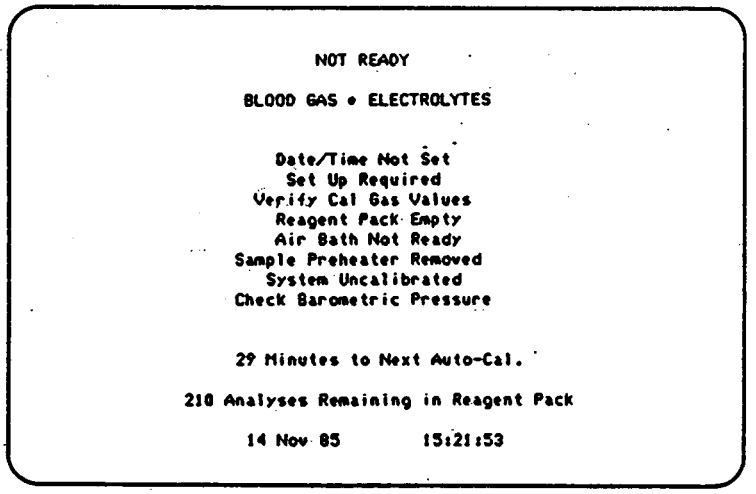
2 PROGRAM INITIALIZATION

This section covers initialization of the program from the READY (NOT READY) FOR ANALYSIS screen and from the Set Up menu. Also, reinitialization after a power loss is covered.

2.1 Analysis Initialization

2.1.1 READY FOR ANALYSIS Initialization

When the NOT READY screen is displayed, the analyzer is not ready to perform an analysis. Correct the displayed error messages as follows:



NOT READY

1. DATE/TIME NOT SET

   Set date and time per Section 3.2.4.

2. SYSTEM SET UP REQUIRED

   An abbreviated set up procedure is outlined here, in which the factory-set set up selections are entered. Refer to Section 2.2 to perform a system program set up to your laboratories' requirements. Default to the factory set-up selections as follows:

   a. Press MENU, entering the MAIN MENU screen.
   b. Press 4, accessing the System Set Up ENTER SYSTEM PASSWORD screen.
   c. Key in 0 (zero), the factory-set password.
   d. Press ENTER.
   e. Press CLEAR 2 times to return to the NOT READY screen.

3. CAL GAS VALUES REQUIRED

   Enter the calibration gas values as follows:

   a. Press MENU, accessing the main menu.
   b. Press 2, accessing the MAINTENANCE MENU screen.
   c. Press 8, accessing the SET CALIBRATION GASES screen.
   d. Set the gas calibration values as read off the gas cylinders (see also Table 7.2), per section 5.1.8.
   e. Press CLEAR 3 times to return to the NOT READY screen.

4. REAGENT PACK EMPTY

Start up the Reagent Pack as follows:

a. Press MENU, accessing the MAIN MENU screen.
b. Press 2, accessing the MAINTENANCE MENU screen.
c. Press 9, accessing the REAGENT PACK screen.
d. Check that there is a full Reagent Pack in the analyzer.
e. Enter the number of analyses expected from the Reagent Pack per Section 5.1.9.
f. Press ENTER, setting the analyses remaining counter.
g. Press CLEAR 3 times to return to the NOT READY screen.

5. AIRBATH NOT READY

The Airbath temperature has not stabilized at 37° C. Check that the door is closed. When the Airbath temperature stabilizes at 37° C, this message will disappear.

6. SAMPLE PREHEATER NOT READY

The Sample Preheater temperature has not stabilized at 37° C. Verify that the assembly is firmly seated on the electrical connector and that the door is closed. When the Sample Preheater temperature stabilizes at 37° C, this message will disappear.

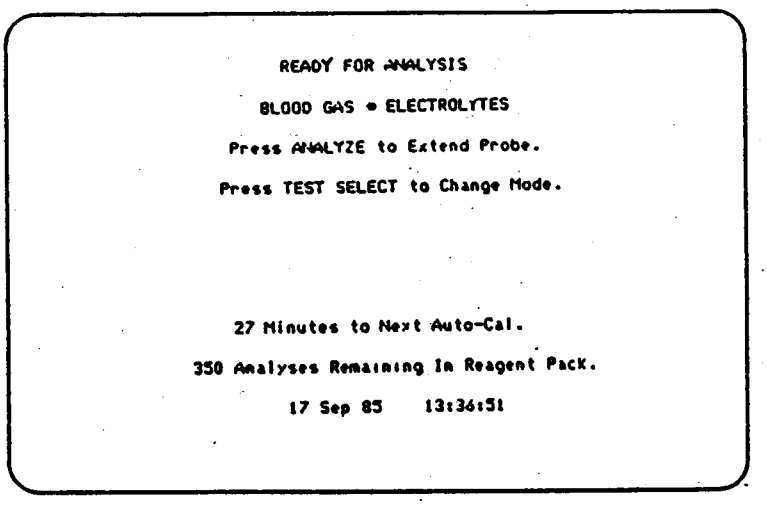
7. SYSTEM UNCALIBRATED

Perform a whole blood conditioning cycle per Section 5.1.5 then press CAL, ENTER to initiate a full two-point calibration with gas and liquid calibrators. If the message recurs press CAL, ENTER again to perform a second two-point calibration. If the message still recurs troubleshoot the problem per Section 6.3.

8. CHECK BAROMETRIC PRESSURE

This message will appear if the analyzer has reverted to the Default Barometric Pressure, or if the Manual Barometric Pressure mode has been selected and the power has been off for at least 5 seconds. To clear this message, manually set the Barometric Pressure as described in Section 3.2.3. The Default Barometric Pressure is covered in Section 2.2.7, and the Manual/Auto Barometric Pressure modes are covered in Section 2.2.8.

Upon successful completion of the calibration, the READY FOR ANALYSIS screen will appear signifying that the analyzer is ready to analyze samples.



READY FOR ANALYSIS

The READY FOR ANALYSIS screen is the primary operating screen of the analyzer, displaying information as to:

- Tests selected
- Error messages
- Uncalibrated electrodes
- Time remaining until an analyzer-initiated autocalibration
- Number of tests remaining in Reagent Pack
- Date and time.

2.1.2 Barometer Check

Check the barometric pressure as follows:

1. Press STATUS repeatedly to cycle through the Status screens to the System Status screen.
2. Note the barometric pressure displayed in this screen. The barometric pressure reading should agree within ± 2 mm mercury with a reliable reference value such as a lab barometer or an altitude-corrected weather bureau reading. If the displayed pressure is unacceptable, refer to Section 3.2.3 to change the value.

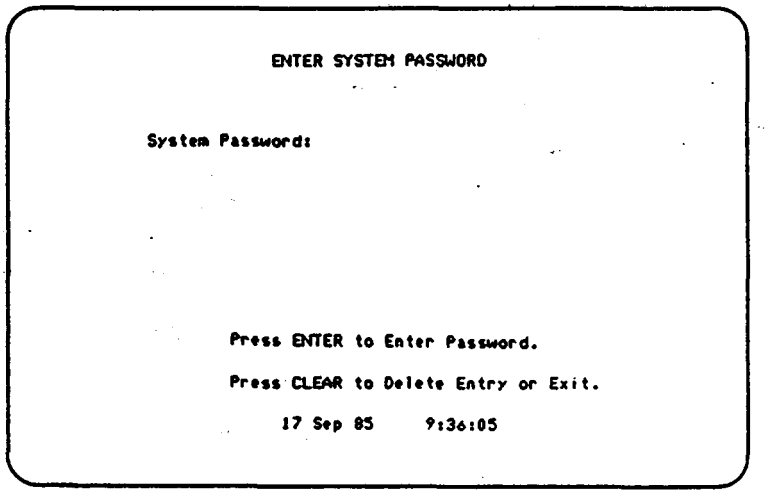
2.2 Set Up Menu

Access the Set Up menu to set up the analyzer to your laboratories' requirements. The menu is also accessed whenever the analyzer loses power with the internal battery discharged (see Section 2.3). The menu is comprised of:

- Default functions, which define what analysis mode, units of measurement, or parameters the system uses (defaults to) unless you tell it otherwise
- Restriction functions which allow (or disallow) analysis modes, and individual, calculated and temperature reporting options
- Specification functions which define number of decimal places reported, offsets, manual or automatic operation, and passwords

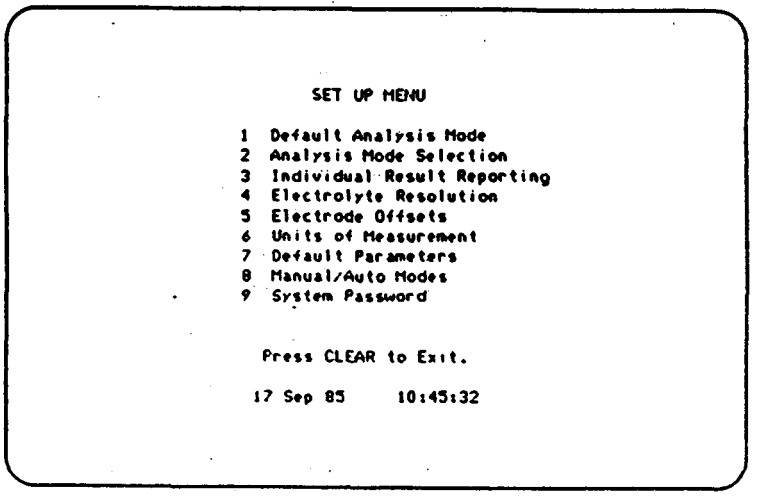
A password, which safeguards the set up parameters, is required to enter the Set Up menu. Set up the system program as follows:

1. From the READY FOR ANALYSIS screen, press MENU to access the Main Menu screen.
2. Press 4, accessing the System Set Up ENTER SYSTEM PASSWORD screen. The screen displays a flashing cursor next to the point for keying in the password.



ENTER SYSTEM PASSWORD

3. Key in the password (a number) and press ENTER. The analyzer is factory set with 0 (zero) as the default password. Upon entry of the correct password, the SET UP MENU screen is displayed.



SET UP MENU

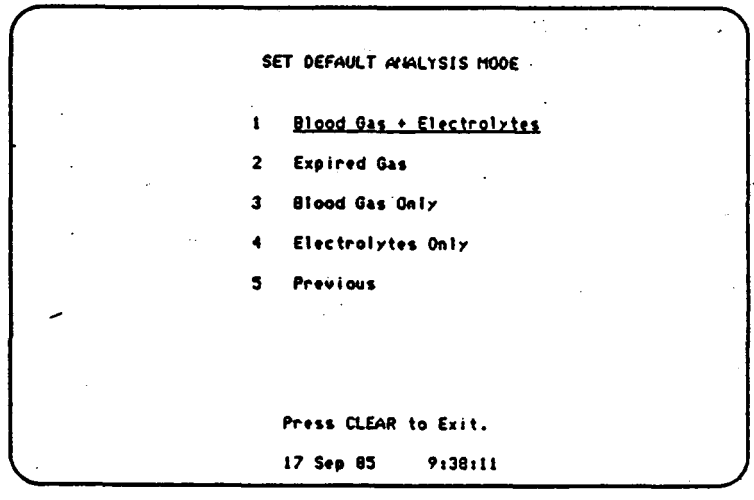
4. See Sections 2.2.1 to 2.2.9 to access the appropriate Set Up screens.
5. Press CLEAR to return to the Set Up menu. Press CLEAR again to return to the Main Menu. Press CLEAR again to return to the READY (NOT READY) FOR ANALYSIS screen.

2.2.1 Set Default Analysis Mode

This screen selects 1 of 5 sets of tests (analysis modes) as the Default Analysis Mode. The operator can change the analysis mode by pressing TEST SELECT, but the analyzer will return to the Default Analysis Mode after one analysis is completed. The Previous Mode (function 5) is a special case: the default analysis mode is defined by the previous analysis mode, which can be selected with the TEST SELECT key.

In this screen, the mode which is highlighted and underlined is the current Default Analysis Mode. Change the Default Analysis Mode as follows:

1. Press 1, accessing the SET DEFAULT ANALYSIS MODE screen.
2. Press the desired number corresponding to Blood Gas and Electrolytes, Expired Gas, Blood Gas Only, Electrolytes Only, or Previous parameter catagory. The selected function is highlighted to identify it as the new default mode.
3. Press CLEAR to return to the Set Up Menu.



SET DEFAULT ANALYSIS MODE

2.2.2 Analysis Mode Selection

This screen sets the allowable analysis mode for selection by the TEST SELECT key. This selection disallows unwanted testing and the attendant expenses in time and reagents. The On or Off state of an analysis mode, as highlighted next to the specific function, determines which analysis modes are allowed to be chosen by TEST SELECT. The tests performed and calculated results available for the different modes are given in Table 2.1.

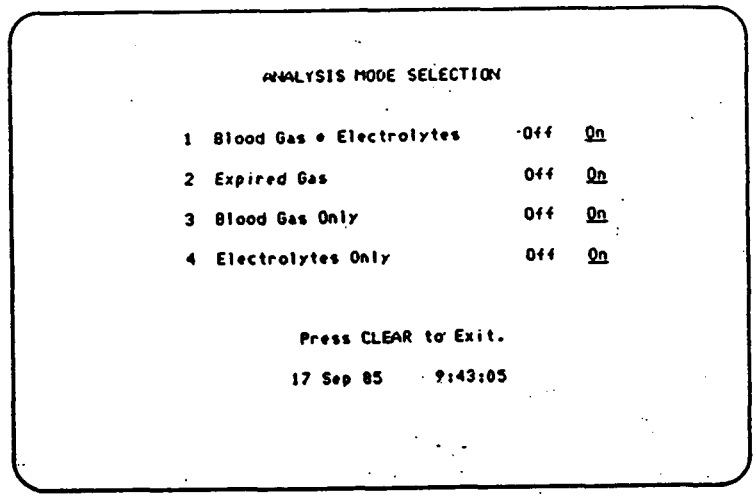
Table 2.1 Analysis Mode Tests

	Blood Gas and Electrolytes	Expired Gas	Blood Gas	Electrolytes Only
Measured Tests				
Sodium:	X			X
Potassium:	X			X
Calcium:	X			X
pH:	X		X	X
PCO_2:	X	X	X	
PO_2:	X	X	X	
Hct:	X			
Calculated Values				
O2 Saturation:	X		X	
Base Excess Blood:	X		X	
Base Excess ECF*:	X		X	
Bicarbonate:	X		X	
Std. Bicarb.Conc.:	X		X	
Total CO_2:	X		X	
O_2 Content:	X		X	
Normalized Ca^{++}:	X			X
Hemoglobin:	X			X**

* ECF = Extracellular Fluid
** Default value

Select the analysis modes as follows:

1. Press 2, accessing the ANALYSIS MODE SELECTION screen.
2. Press the number of the analysis mode you wish to suppress. The highlighting moves to the Off column signifying that this analysis mode is suppressed. To restore an analysis mode that has been suppressed, press the number again to move the highlighting back to the On column.



ANALYSIS MODE SELECTION

3. Press CLEAR to return to the SET UP MENU screen.

2.2.3 Individual Result Reporting

The Individual Result Reporting function in the Set Up menu allows access to 3 screens. The Individual, Calculated, and Blood Gas Measured Results Reporting screens, described as follows, restrict individual and calculated results reporting and temperature reporting options.

Individual Result Reporting - If calcium, a measured parameter, is Off in this screen, it cannot be selected On during an analysis and so cannot be displayed or printed out for an analysis. If calcium is On, then it can be turned On or Off during an analysis (see Section 3.1.2.1, Steps 5 - 7). For the effect of measured result reporting changes on the calculated results reported, refer to Table 2.2.

Calculated Results - If BE-ECF, a calculated parameter, is Off in this screen, it cannot be selected On during an analysis and so cannot be displayed or printed out for an analysis. If BE-ECF is On, then it can be turned On or Off during an analysis (see Section 3.1.2.1, Steps 5 - 7). For calculated result reporting changes which affect the calculated results reported, refer to Table 2.2.

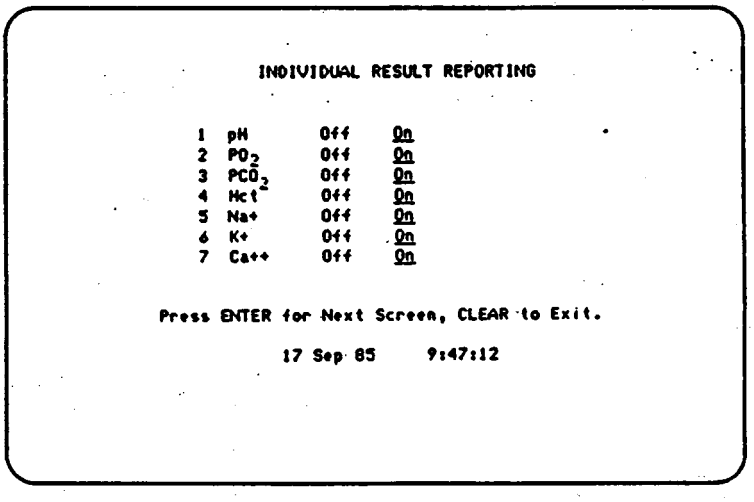
Blood Gas Measured Results - This screen selects from 2 display and print options. Selecting Off results in the display and printing of results at patient temperature only. Selecting On results in the display and printing of results at both the patient temperature and 37.0°C. If this screen is not accessed during set up, results will be displayed and printed at the patient temperature only.

Table 2.2 Result Suppression Effects

Suppressed Parameter	Calculated Result Suppressed
Na, K	None
Ca^{++}	nCa^{++}
pH	All
PCO_2, PO_2	All except nCa^{++}
HCO_3^-	TCO_2, BE-B, BE-ECF, SBC, O_2Sat, O_2Ct
O_2Sat	SBC, O_2Ct

Select Individual Result Reporting options as follows:

1. From the Set Up menu, press 3, accessing the measured INDIVIDUAL RESULT REPORTING screen.
2. Press the number corresponding to the parameter you wish to supress reporting. The highlighting moves to the Off column signifying that the parameter has been suppressed. To restore a parameter that has been suppressed, press the corresponding number again to move it back to the On column.

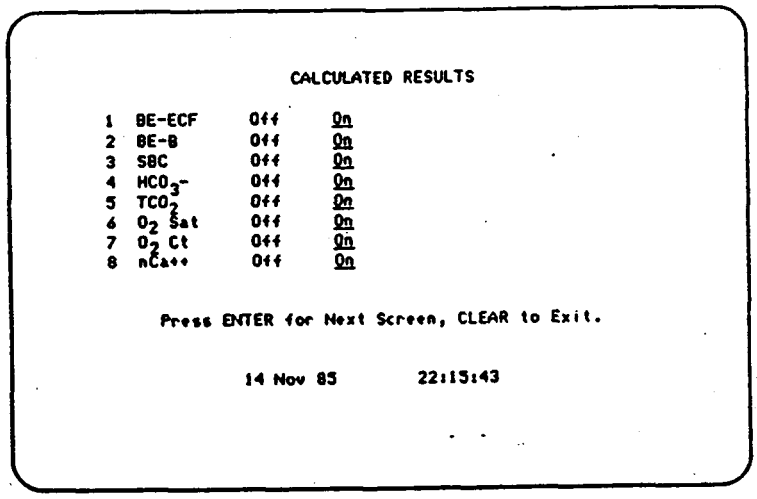


INDIVIDUAL RESULT REPORTING

3. Repeat Step 2 for other parameters you wish to suppress.
4. Press ENTER and continue with Step 2 of the following procedure for Calculated Results, or press CLEAR to return to the Set Up menu.

Select Calculated Result options as follows:

1. From the Set Up menu, press 3, ENTER, accessing the CALCULATED RESULT screen.
2. Press the number corresponding to the parameter you wish to supress reporting. The highlighting moves to the Off column signifying that the parameter has been suppressed. To restore a parameter that has been suppressed, press the corresponding number again to move it back to the On column.

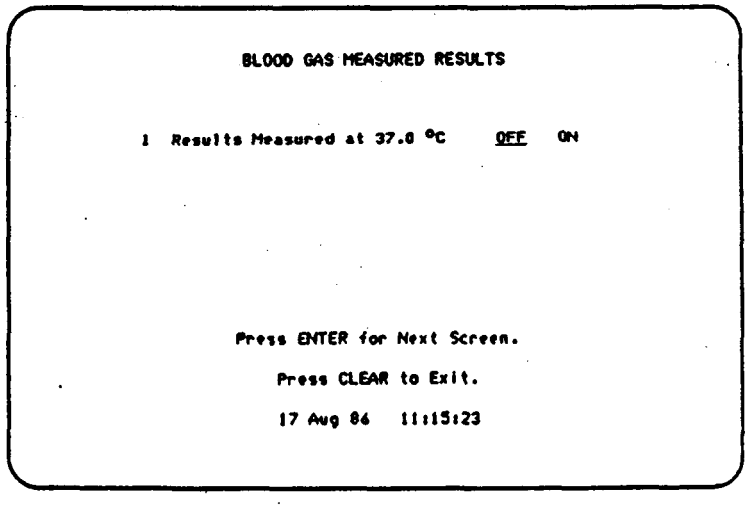


CALCULATED RESULTS

3. Repeat Step 2 for other parameters you wish to suppress.
4. Press ENTER and continue with Step 2 of the following procedure for Blood Gas Measured results, or press CLEAR to return to the Set Up menu.

Select Blood Gas Measured Result options as follows. Refer to 3.1.2.1, Steps 9 & 10 for the 2 sets of results screens that are possible, and to Figure 3.2 for the 2 possible printouts.

1. From the Set Up menu, press 3, ENTER, ENTER, accessing the BLOOD GAS MEASURED RESULT screen.
2. Press 1 to move the highlighting to On, displaying and printing results at both 37.0 ^{o} C and patient temperature. Press 1 again to move the highlighting to Off, displaying and printing results at patient temperature only.



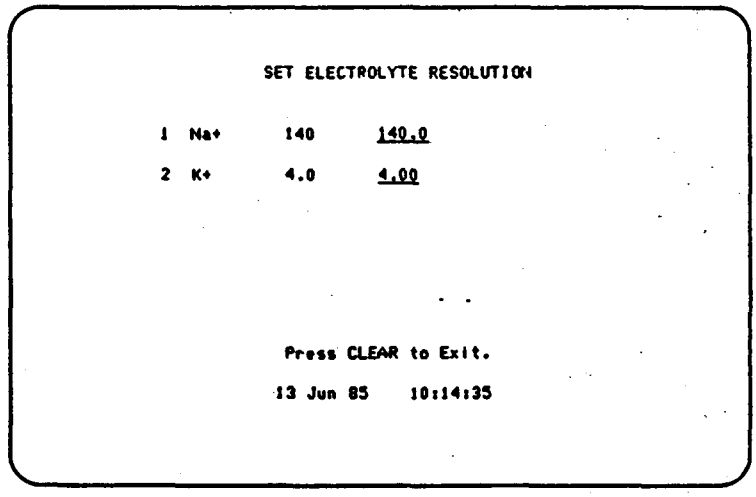
BLOOD GAS MEASURED RESULTS

3. Press ENTER to move to the INDIVIDUAL RESULTS REPORTING screen and continue with Step 2 of this screen, or press CLEAR to return to the Set Up menu.

.2.4 Set Electrolyte Resolution

is screen sets the number of decimal places expressed for Na and K results isplay or printout. Values are rounded to the decimal place shown. (The alues shown are examples only.) Set electrolyte resolution as follows:

1. Press 4, accessing the SET ELECTROLYTE RESOLUTION screen.
2. Press the number corresponding to the desired electrolyte, moving the highlighting to the other resolution value and signifying the new resolution.
3. Repeat Step 2 for other electrolytes as desired.
4. Press CLEAR to return to the SET UP MENU screen.



SET ELECTROLYTE RESOLUTION

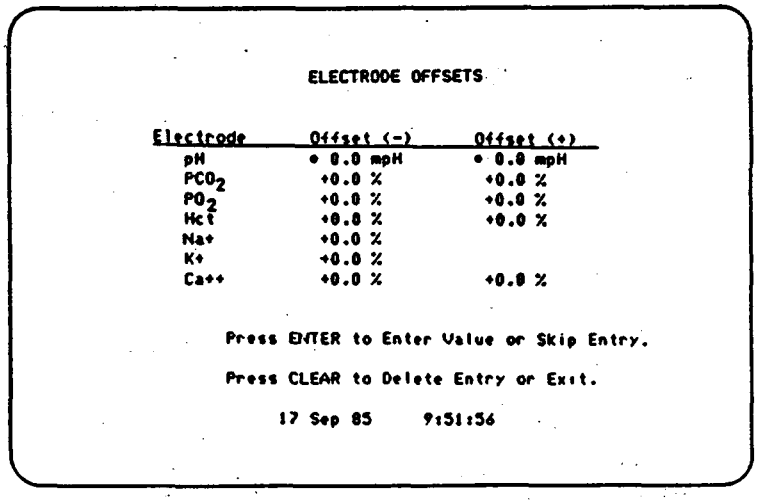
2.5 Electrode Offsets

The values entered in this screen offset the measured results by the selected percentage. This is used to correlate the results to the other methodologies currently being used in your laboratory.

NOTE: Use considerable care in establishing the offset values for your lab.

Enter electrode offset values as follows:

1. Press 5, accessing the ELECTRODE OFFSET screen.
2. Press ENTER repeatedly to move the cursor through the available positive or negative values (no positive offsets are available for Na and K).
3. Key in the desired offset percent value to 1 decimal place next to the original parameter. The offset ranges are as follows in Table 2.3.



ELECTRODE OFFSETS

Table 2.3 Offset Ranges

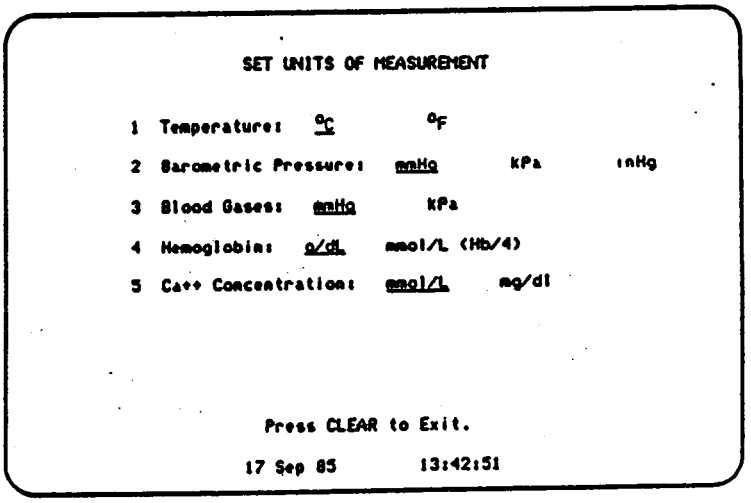
PO_2	± 6 %
PCO_2	± 5 %
pH	± 20 mpH units (1 mpH unit = .001 pH units)
Hct	± 5 %
Na	- 7 %
K	- 7 %
Ca^{++}	± 5 %

4. Press ENTER to replace the original offset percent value with the new value. To cancel an entry press CLEAR before pressing ENTER.
5. Repeat Steps 2 through 4 for each value.
6. Press CLEAR to return to the SET UP MENU screen.

2.2.6 Set Units Of Measurement

This screen sets the units of measurement for various parameters to the units of measurement reported by your laboratory. The units of measurement which are highlighted on this screen will be the units used on all screens and on all results. Select the Units of Measurement as follows:

1. Press 6, accessing the SET UNITS OF MEASUREMENT screen.
2. Press the number corresponding to the desired units to change.
3. Pressing this number again moves the highlighting to the next consecutive value in a cyclic fashion.
4. Repeat Steps 2 and 3 to change any other units.
5. Press CLEAR to return to the SET UP MENU screen.



SET UNITS OF MEASUREMENT

2.2.7 Set Default Parameters

This screen gives you the option of selecting Patient Data, Printer Subsystem, and Communications Subsystem default parameters as follows:

Patient Data

The Patient Data default values for the analyzer are:

- Temperature - 37.0° C,
- Hemoglobin - 14.3 g/dL
- Barometric Pressure - 760 mm/Hg

Unless the actual patient temperature is keyed in, using the PATIENT DATA screen, a default temperature of 37.0° C (normal body temperature) will be used for all measured and calculated results. The hemoglobin value of 14.3 g/dL is factory set and is the default hemoglobin value. The default hemoglobin value will be used in calculating the calculated parameters only when the actual hemoglobin value is not entered through the patient data screen, and when, due to a hematocrit error, an analyzer-calculated hemoglobin is not available. The Hemoglobin used in an analysis can be identified by subscript as follows:

- Hb_c - Calculated Hemoglobin
- Hb_d - Default Hemoglobin
- Hb_e - Entered Hemoglobin (From Patient Data Screen)

The default barometric pressure is used when the barometer fails. When this happens, the NOT READY screen is displayed (or if in an analysis, the error code is displayed) and the relevant results are displayed flashing, and printed with a question mark.

Printer Subsystem

The Printer Subsystem allows you to set the number of results copies printed each time a manual or automatic results printout is performed. Choose from 1 to 3 copies. The Print Density allows you to choose the darkness of the printout print.

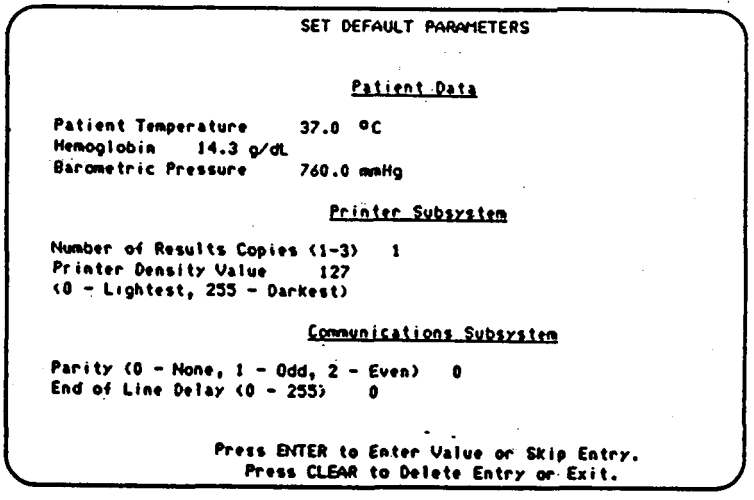
NOTE: Higher print density values will result in earlier printhead failure.

Communications Subsystem

The Communications Subsystem defines the parity and end-of-line settings. Parity selection allows you to match even, odd, or no parity to an external devices' parity requirements. The end of line setting enables you to adapt the Stat Profile 1 data transmission rate to the requirements of an external device. See the Stat Profile Communications Interface Manual for more details on these settings.

Set default parameters as follows:

1. Press 7, accessing the SET DEFAULT PARAMETERS screen.
2. Press ENTER to cycle the cursor through the available parameters.
3. Key in the new default value, which appears next to the original value.
4. Press ENTER to replace the original value with the new default value. To cancel an entry, before pressing ENTER, press CLEAR.
5. Press CLEAR to return to the SYSTEM SET UP Menu.



SET DEFAULT PARAMETERS

2.2.8 Set Manual/Auto Modes

This screen allows you to set certain features on the analyzer to occur automatically without operator interaction (AUTO), or to occur manually, requiring operator manual access via the keypad (MANUAL). For example, the AUTO choice for the PATIENT DATA screen will result in automatic display of the Patient Data screen during an analysis without requiring operator interaction. The MANUAL choice requires you to manually access the Patient Data screen. A summary of the manual and automatic modes available in the SET MANUAL/AUTO MODES screen is as follows:

1. Patient Data Screen

   AUTO - the Patient Data Screen will automatically appear with each analysis.

   MANUAL - you must press PATIENT DATA to access the Patient Data screen during an analysis.

2. Results Printout

   AUTO - results printout will automatically occur when the results screen is displayed at the end of an analysis.

   MANUAL - you must press PRINT while displaying a results screen to obtain an analysis results printout.

3. Results Transmission

AUTO - results will automatically be transmitted to an external printer or computer when you exit from a results screen by pressing CLEAR or ANALYZE.

MANUAL - results transmission will only occur if Manual Transfer function is accessed in Subsystem Test Communications (Section 6.4.8).

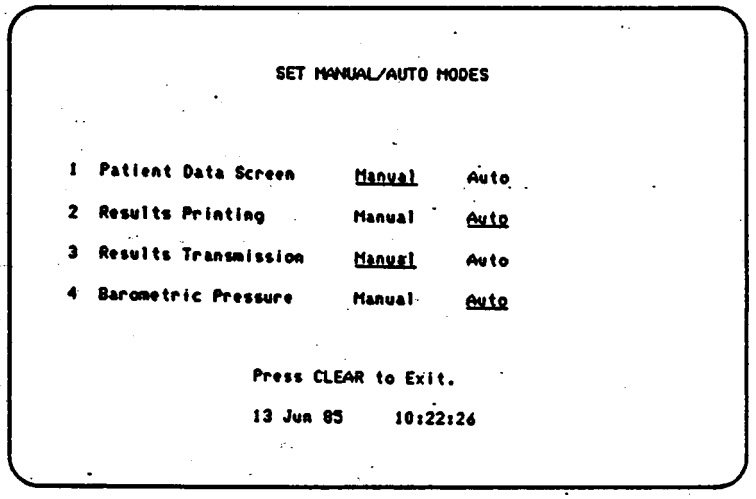
4. Barometric Pressure

AUTO - the system barometer will monitor barometric pressure used for results calculation.

MANUAL - the system barometer is deactivated. You must enter an external manual Barometric Pressure (Section 3.2.3).

Set the MANUAL/AUTO modes as follows:

1. Press 8, accessing the SET MANUAL/AUTO MODES screen.
2. Press the number of the corresponding function to be changed to move the highlighting from manual to auto or vice-versa. The highlighting moves to the other column signifying that the mode has been changed. To change the mode back, press the number again.
3. Press CLEAR to return to the SET UP MENU.

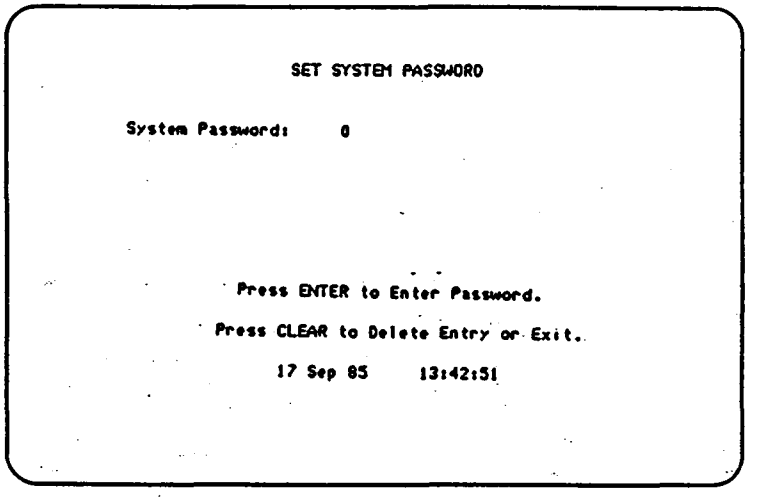


SET MANUAL/AUTO MODES

2.2.9 Set System Password

This screen allows for the password for entering the Set Up Menu to be changed from the NOVA factory set password of 0 (zero) to a password desired by the lab. The new password can be kept confidential to ensure that proper analyzer set up is maintained. Set the system password as follows:

1. Press 9, accessing the SET SYSTEM PASSWORD screen.
2. Key in the new password (a numeric value up to 4 digits long) at the cursor.
3. Press ENTER to enter the new password. To cancel an entry before pressing ENTER, press CLEAR.
4. Press CLEAR to return to the Set Up Menu.



SET SYSTEM PASSWORD

NOTE: If you lose or forget your password, you will not be able to access the Set Up menu. Unplugging the analyzer will not help; the password is retained in permanent memory. To regain access to the Set Up menu, contact NOVA Technical Service.

.3 Instrument Power Loss

a power loss of up to 5 seconds occurs, any analysis in progress or other equence in progress will be terminated. No other effects will occur in this ituation. If a power loss of over 5 seconds duration occurs however, an internal battery acts to retain the:

- Set Up values
- Calibration Gas Values
- Barometer Offset
- Number of Analyses Remaining in the Reagent Pack
- Previous Results

ime and date, calibration slopes, pending analysis results and patient data, peration menu values (other than the barometer offset) and error codes will e lost. Upon return of power, set the time and date, perform a calibration, nter any desired operation menu values, and resume normal operation.

f the analyzer has been set up previously but upon power loss SET UP REQUIRED ppears on the READY FOR ANALYSIS screen, the internal battery has discharged nd no instrument function values are saved. The password is reset to 0 zero) in this case, but, after accessing the Set Up menu and performing the et up procedure, normal operation can resume. Contact NOVA Technical Service or a Service Representative to replace the battery.

3 OPERATION

This section covers analysis and calibration.

3.1 Analysis

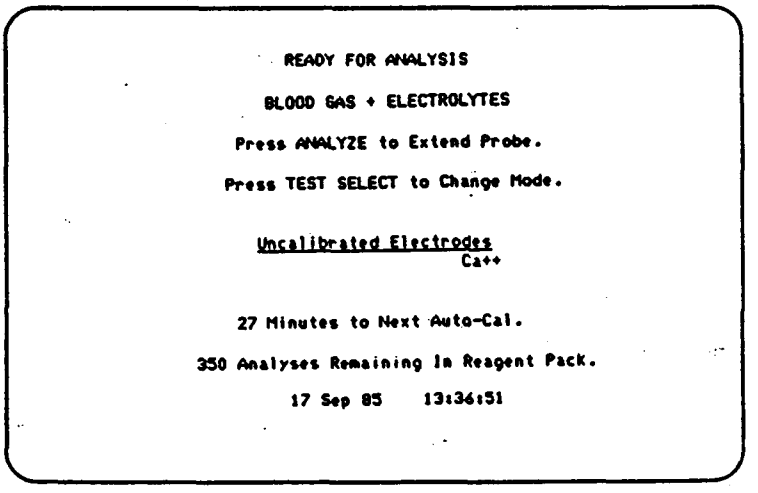
Analysis is initiated by pressing ANALYZE at any time the analyzer is idle. You will only get meaningful results, however, if the analyzer is ready as evidenced by the green Instrument Status Light and the READY FOR ANALYSIS screen. If you need to access any functions in the Operation Menu (as at the start of a shift, such as Test Sequence Counter, Barometer check or Date/Time setting) perform these functions as explained in Section 3.2 before pressing ANALYZE.

Analysis begins with the selection (if necessary) of the appropriate Analysis Mode. The remaining steps are outlined under the specific analysis cycle.

3.1.1 Analysis Mode Selection

Analysis mode selection matches the sample type to the appropriate system cycle. The current analysis mode is displayed underneath READY FOR ANALYSIS on the READY FOR ANALYSIS screen. The available sample analysis modes are as follows:

- Blood Gas + Electrolytes
- Expired Gas
- Blood Gas
- Electrolytes



READY FOR ANALYSIS - BLOOD GAS + ELECTROLYTES Analysis Mode

A default analysis mode is set upon installation. To change the mode from this default, press CLEAR until the READY FOR ANALYSIS screen is displayed, then press TEST SELECT until the desired mode is selected. For example, if you receive a sample for electrolytes only and the current analysis mode is Blood Gas + Electrolytes, press TEST SELECT 3 times to select the Electrolytes analysis mode. Any mode selected in this way will be displayed blinking on the screen to show that it is not the default analysis mode.

(If TEST SELECT does not access one of the 4 modes, the mode is being suppressed. Access the ANALYSIS MODE SELECTION screen from the SET UP menu (Section 2.2.2) to restore the analysis mode for TEST SELECT accession.)

.1.2 Analysis Cycles

ples can be analyzed from syringes, vacuum tubes, expired air bags, capil-ries, or sample cups. A minimum of 250 ul of sample is required.

.1.2.1 Syringe, Vacuum Tube or Sample Cup Sampling

1. Press ANALYZE. The sampler probe extends and the CRT displays the position sample screen.
2. Present the sample container to the sampler probe (Syringe shown in Figure 3.1) and press ANALYZE a second time to aspirate the sample. Do not allow the Sampler Probe to touch the base of the syringe plunger or the bottom of the sample cup or tube.

NOTE: Press ANALYZE within 30 seconds after initially pressing ANALYZE (Step 1).

BLOOD GAS + ELECTROLYTES

POSITION SAMPLE FOR ASPIRATION

Press ANALYZE When Ready.

Press CLEAR to Abort.

13 Jun 85 10:35:39

POSITION SAMPLE

CAUTION: Do not touch the Analyzer Compartment door during an analysis. Electronic interference and temperature instability could result.

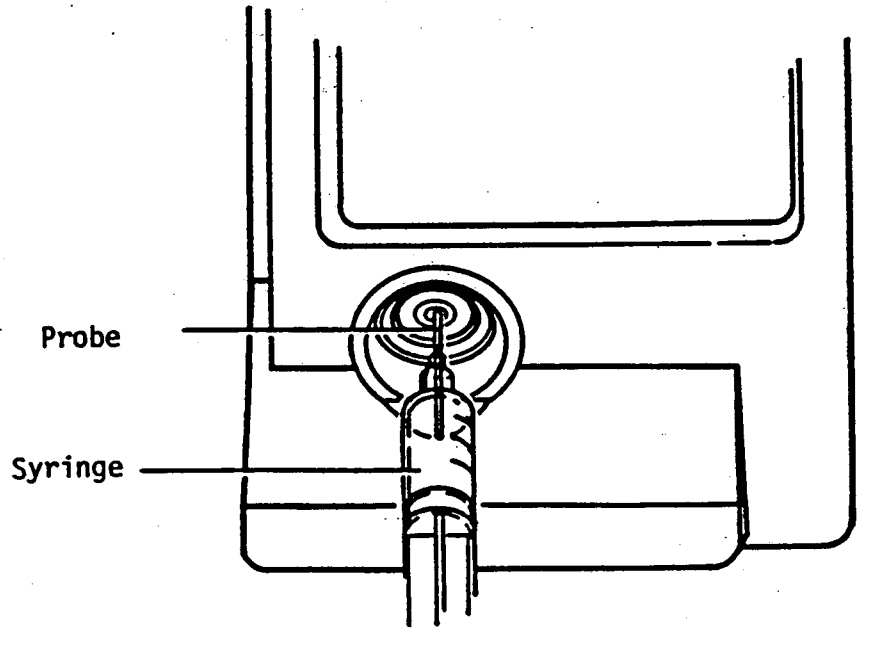
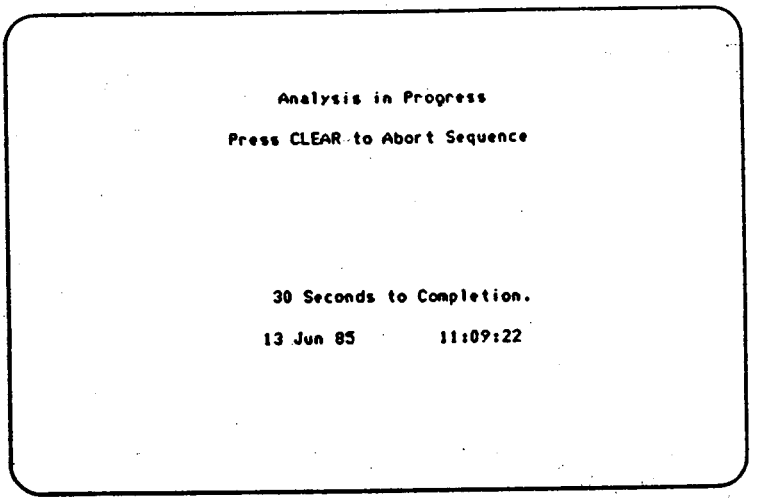


Figure 3.1 Syringe Sample Presentation

3. When the probe retracts, withdraw the sample (if the sample is from a syringe, expel the bubble of air from the syringe and cap it). The CRT displays the Analysis In Progress screen.

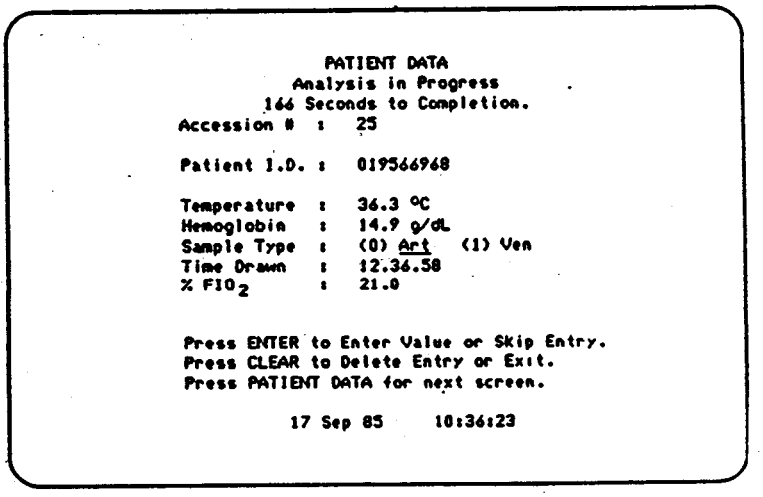


ANALYSIS IN PROGRESS

NOTE: If an insufficient sample is detected or a major fluid flow error occurs during analysis, the system will abort the analysis and flush the system.

4. As soon as the Analysis In Progress screen is displayed, press PATIENT DATA (if the screen was not set up to be automatically displayed) to access the Patient Data screen. Enter the patient data, and if necessary, change the individual and calculated results reporting as follows.

a. Press ENTER repeatedly to cycle through the choices to the desired choice.
b. Key in the appropriate value using the keypad.
c. Press ENTER to enter the value and also to move the cursor to the next choice.
d. Press CLEAR to delete an erroneous entry.



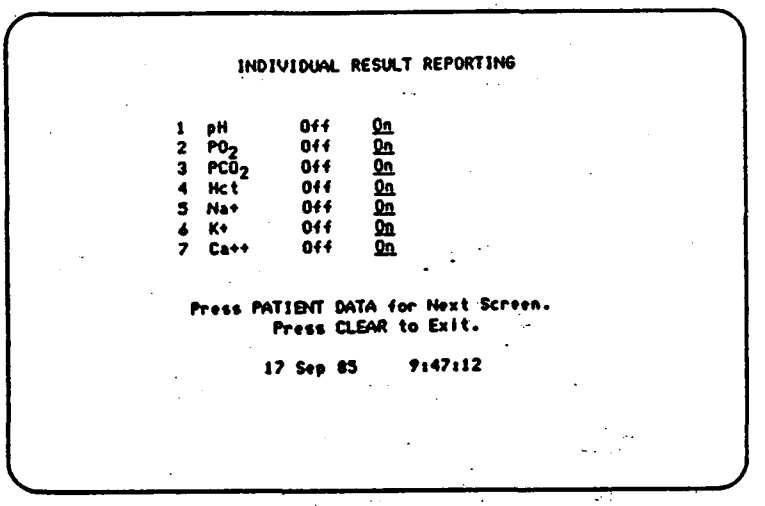
PATIENT DATA

e. Repeat Steps a - d as needed, then press CLEAR to exit the screen or PATIENT DATA to access the Individual Result Reporting screen as in Step 5.

NOTE: The status display on the Patient Data screen shows the state of the analysis (In Progress, Completed, Aborted, etc.) and the time remaining to completion. If the analysis has already finished when you exit from the Patient Data screen, the current Patient Data values will be used to compute the Corrected and Calculated results and the Measured Results screen will be displayed. If the Auto Results Print mode is selected (Section 2.2.8), results will be printed.

5. From the Patient Data screen, press PATIENT DATA to access the Individual Result Reporting screen. This screen allows you to change the setting of any of the measured parameters or calculated results for the duration of a single patient test.

   a. Press the function number of the desired measured parameter you wish to move to the Off position. Off will be underlined and highlighted.
   b. The parameter is now turned off and will not be reported. Any calculated results based on this value would also not be reported. Turn On a parameter that is Off by pressing the appropriate function number of the desired measured parameter.

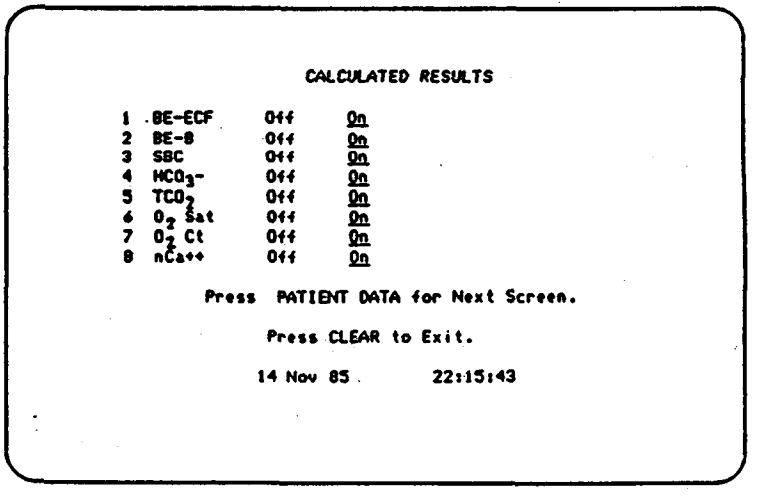


INDIVIDUAL RESULTS

NOTE: Test Select and Set Up menu restriction functions define which parameters can be changed.

   c. Repeat Step 5 until all desired parameters are changed.

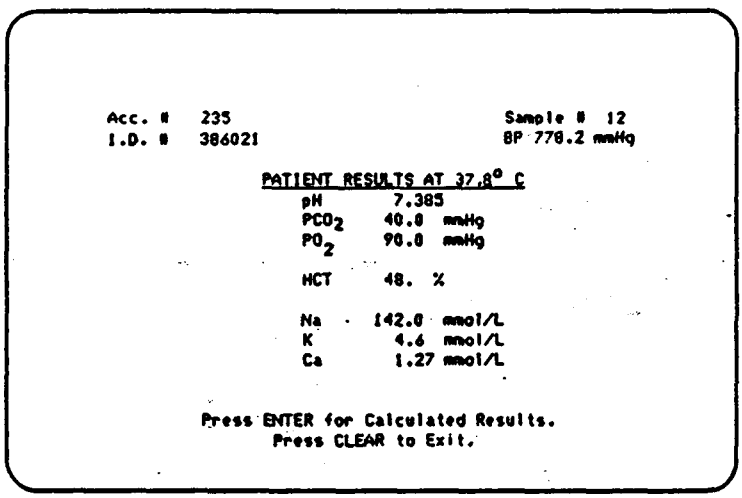
6. Press PATIENT DATA again, accessing the CALCULATED RESULTS screen.
7. Repeat Step 5, adapted for this screen, until all desired parameters are changed.
8. Press CLEAR to exit this screen.



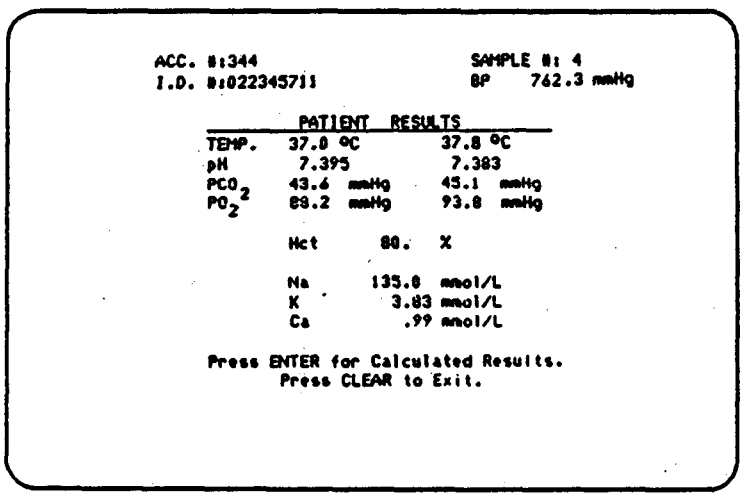
CALCULATED RESULTS

9. Measured results are displayed upon sequence completion, and measured and calculated results are printed out (see Figure 3.2).

NOTE: Any results suppressed in the Set Up menu or in Individual Result Reporting will not be displayed or printed.



Measured Results (Patient Temperature)



Measured Results (Patient Temperature and 37.0°C)

10. Press ENTER to display the calculated results.

Calculated Results

```
Acc. # 235                          Sample # 12
I.D. # 386021                       BP 773.3 mmHg

                CALCULATED VALUES

Hb              43.0 g/dL
BE-ECF          -3.1 mmol/L
BE-B            -1.4 mmol/L
SBC             23.2 mmol/L
HCO3-           25.4 mmol/L
TCO2            27.5 mmol/L
O2 Sat          80.6 %
O2 Ct            2.0 ml/L
nCa++            1.30 mmol/L

Press ENTER for Measured Results.

Press CLEAR to Exit.
```

Printout (Patient Temperature)

```
STAT PROFILE 1

22 May 86   14:21

Accession #:
123
Patient I.D.:
125635897
Arterial Sample
Time Drawn: 09.32
FIO2: 21

Patient Temp 36.5 °C
pH          7.373
PCO2       46.1   mmHg
PO2       100.3   mmHg

Hct        34.    %

Na+       135.5   mmol/L
K+          3.83  mmol/L
Ca++        1.03  mmol/L

Hbc        11.2   g/dL
BE-ECF   + 1.6   mmol/L
BE-B     - 0.0   mmol/L
SBC        24.4   mmol/L
HCO3       26.7   mmol/L
TCO2       28.1   mmol/L
O2Sat      97.1   %
O2Ct        1.6   ml/L
nCa++       1.02  mmol/L
```

Printout (Patient Temperature and 37.0°C)

```
STAT PROFILE 1

21 May 86   13:12

Accession #:
15
Patient I.D.:
148020365
Arterial Sample
Time Drawn: 11.56
FIO2: 25

Measured at 37.0 °C
pH          7.288
PCO2       64.0   mmHg
PO2       104.0   mmHg

Corrected to 36.5 °C
pH          7.295
PCO2       62.7   mmHg
PO2       101.1   mmHg

Hct        41.    %

Na+       127.2   mmol/L
K+          3.62  mmol/L
Ca++        0.89  mmol/L

Hbc        13.6   g/dL
BE-ECF   + 4.1   mmol/L
BE-B     - 3.0   mmol/L
SBC        21.8   mmol/L
HCO3       30.9   mmol/L
TCO2       32.9   mmol/L
O2Sat      97.1   %
O2Ct       18.3   ml/L
nCa++       0.83  mmol/L
```

Figure 3.2 Sample Analysis Printouts

11. Press ENTER again to redisplay the measured results, if desired.
12. You may recalculate results, entering a new patient temperature and/or hemoglobin. Entering a new patient temperature will cause new pH, PCO_2, and PO_2 values to be calculated. Entering a new hemoglobin value will cause those calculated parameters dependent on hemoglobin to be recalculated.

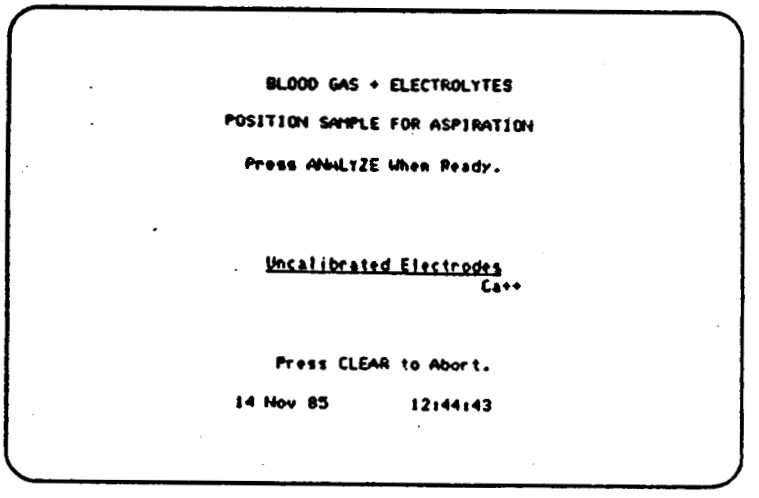
    a. From the Measured or Calculated Results screen, press PATIENT DATA to display the Patient Data entry screen. (If a results screen is not displayed, from the READY FOR ANALYSIS screen press PATIENT DATA).
    b. Press ENTER repeatedly to cycle through the choices to the desired choice.
    c. Key in the appropriate value using the keypad. Press CLEAR to delete an erroneous entry before keying in the new entry.
    d. Press ENTER to enter the value and also to move the cursor to the next choice.
    e. Repeat Steps b - d as needed.
    f. Press CLEAR to display the recalculated results.

13. Press CLEAR to return to the READY FOR ANALYSIS screen.

3.1.2.2 Capillary Sampling

NOTE: Use a capillary tube of at least 280 microliters overall capacity.

1. Fit the Capillary Adapter to the tip of the capillary tube, sliding the base of the adapter over the narrow end of the capillary tube (Figure 3.2).
2. Press ANALYZE. The Sampler probe extends and the CRT displays the Position Sample screen.
3. Fit the adapter-capillary unit to the Sampler Probe tip, allowing the capillary tube and Sampler Probe to meet flush. Hold the capillary so that it is in line with the Sampler Probe. Continue to hold the capillary for the next step.



POSITION SAMPLE

CAUTION: In the following step, ensure that the capillary remains in line with the probe. Misalignment may cause inadequate aspiration.

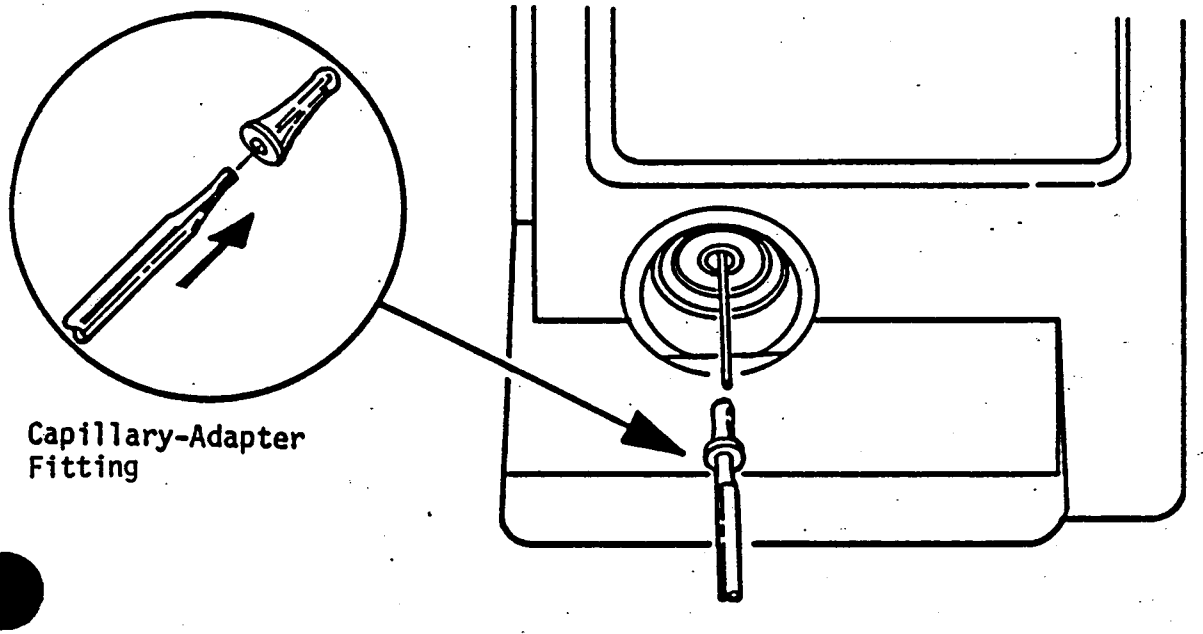


Figure 3.3 Capillary-Adapter Fitting

NOTE: Press ANALYZE within 30 seconds after initially pressing ANALYZE (from Step 2).

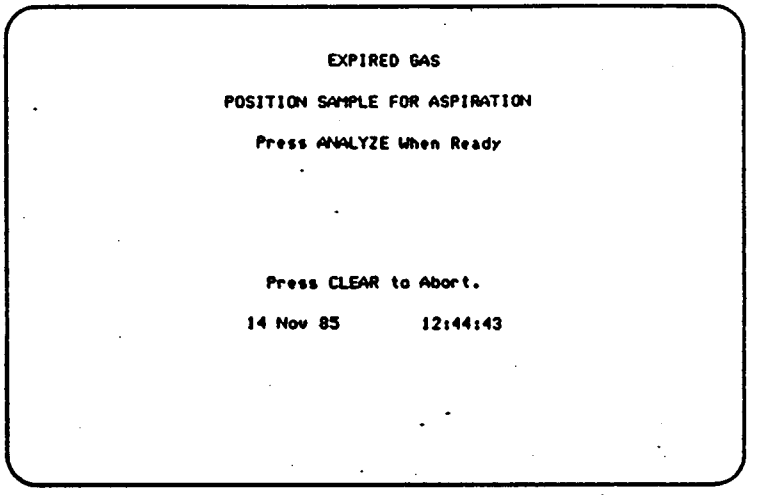
4. Press ANALYZE. When the Sampler Probe retracts, allow the adapter to slide off the Sampler Probe. The CRT displays the Analysis in Progress screen.

CAUTION: Do not touch the Analyzer Compartment door during an analysis. Electronic interference and temperature instability could result.

5. Continue with Step 4 of the Syringe, Vacuum Tube, or Sample Cup Sampling procedure (Section 3.1.2.1).

3.1.2.3 Expired Gas Sampling (PCO_2 and PO_2)

1. Press ANALYZE. The sampler probe extends and the CRT displays the Position Sample screen.



POSITION SAMPLE

2. Slide the bag over the tip of the Sampler Probe, maintain a slight pressure on the bag, and immediately proceed to Step 3.
3. Press ANALYZE, and when the probe retracts, allow the probe to slide off the bag. The Analysis in Progress screen is displayed.

NOTE: Press ANALYZE within 30 seconds after initially pressing ANALYZE (from Step 1).

> CAUTION: Do not touch the analyzer compartment door during an analysis sequence. Electronic interference and temperature instability could result.

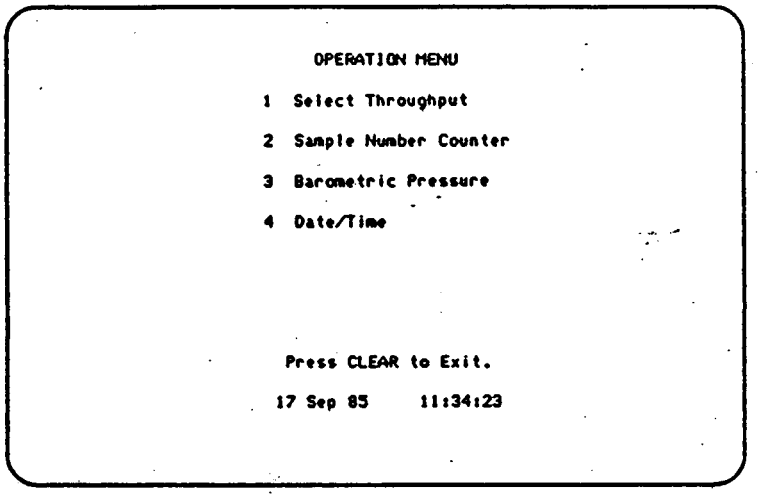
4. Continue with Step 4 of the Syringe, Vacuum Tube, or Sample Cup Sampling procedure (Section 3.1.2.1).

NOTE: The Expired Gas Measured and Calculated results will not include Electrolytes, Hematocrit, pH and the associated results from the Calculated Results screen.

3.2 Operation Menu

Access the operation menu to perform routine operating functions. (Set up parameters, accessed in the Set Up Menu define the less commonly changed default parameters and are usually set only at installation.) Access the Operation Menu as follows:

1. From the READY FOR ANALYSIS screen, press MENU, accessing the MAIN MENU screen.
2. Press 1, accessing the OPERATION MENU screen.
3. See the following Sections to set the appropriate operation parameter. If you wish to exit any operation parameter, press CLEAR to return to the OPERATION MENU screen. Press CLEAR again to return to the MAIN MENU screen. Press CLEAR once more to return to READY (NOT READY) FOR ANALYSIS screen.

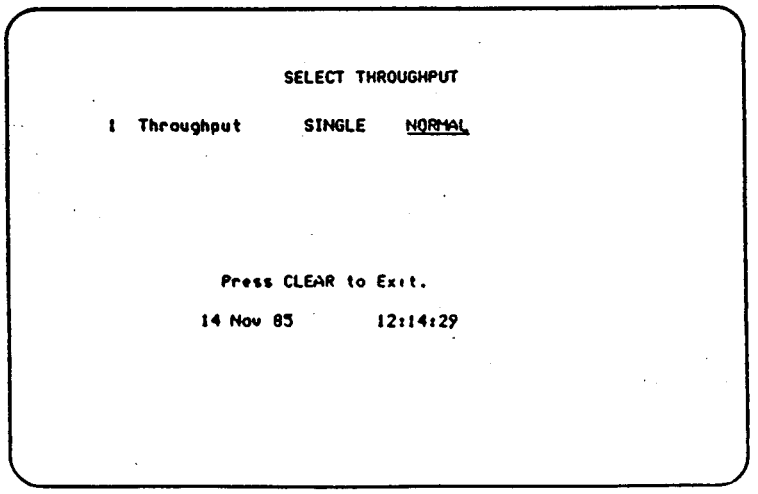


OPERATION MENU

3.2.1 Select Throughput

This screen selects either SINGLE or NORMAL throughput, which differ by frequency of one-point calibration. Selecting SINGLE throughput performs a one-point calibration with each analysis. Selecting NORMAL throughput performs a one-point calibration at approximately 30 minutes from the previous one-point calibration. (One-point calibrations are only performed with an analysis.) A one-point calibration will be performed before the time limit, however, if over 15 minutes elapses between sample analyses, if the Analysis Mode is changed, or if an Instability or Drift error occurs. Select the throughput as follows:

1. Press 1, accessing the SELECT THROUGHPUT screen.
2. Press 1, moving the throughput to the alternate throughput rate (when SINGLE is highlighted pressing 1 will move the throughput to NORMAL and vice versa).
3. Press CLEAR to return to the OPERATION MENU screen.

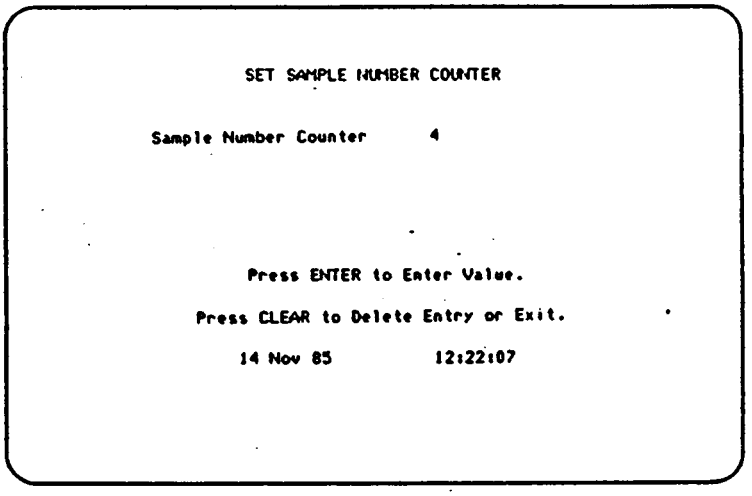


SELECT THROUGHPUT

3.2.2 Set Sample Number Counter

The Sample Number counter is used to monitor the number of samples analyzed over a particular time period, or to provide a sample number for each printout. The counter counts from 0 to 255 and automatically resets at 255. The system resets the counter to 0 at 12:00 a.m. At the beginning of a particular time period set the Sample Number counter to 0 as follows.

1. Press 2, accessing the SET SAMPLE NUMBER COUNTER screen.
2. Key in the desired number (usually 0).
3. Press ENTER, replacing the original value with 0. If you wish to enter a number other than 0, key in that number before pressing ENTER. To cancel the entry, press CLEAR before pressing ENTER.
4. Press CLEAR to return to the OPERATION MENU screen.



SET SAMPLE NUMBER COUNTER

3.2.3 Set Barometric Pressure

The SET BAROMETRIC PRESSURE screen has two functions, dependent on the SET MANUAL/AUTO MODES screen (Section 2.2.8):

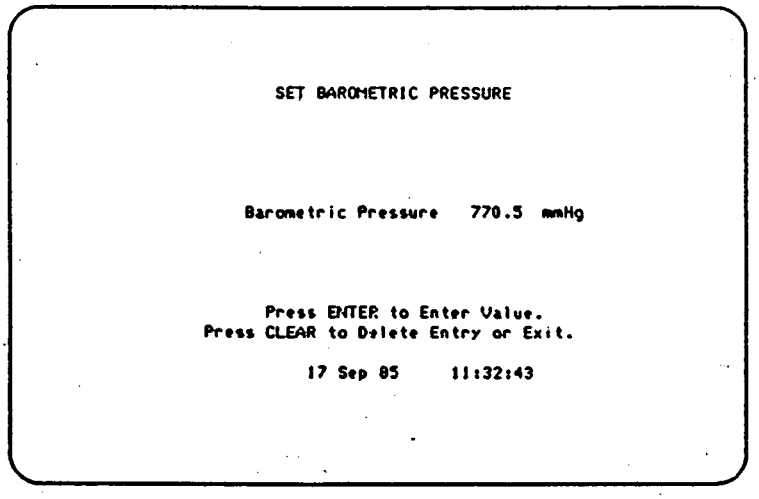
- If the mode is set for AUTO, entering a barometric pressure sets an offset for the system barometer. This calibrates the system barometer to an external barometer.
- If the mode is set for MANUAL, entering a barometric pressure in this screen sets a barometric pressure constant. This screen is usually accessed when the system barometer fails.

The sequence of events upon a system barometer failure is as follows:

1. The system completes any pending analysis using the default barometric pressure value (Sec. 2.2.7).
2. The NOT READY screen is displayed with the CHECK BAROMETRIC PRESSURE status message.
3. The system switches the Barometric Pressure from AUTO to MANUAL.
4. The operator enters the Set Barometric Pressure screen to set an external barometric pressure constant until the barometer problem is solved. When the system barometer is again functional, the operator must set the system to Barometric Pressure AUTO (Section 2.2.8).

et the barometric pressure as follows:

1. Press 3, accessing the SET BAROMETRIC PRESSURE screen.
2. Key in the external barometer barometric pressure, keying in a reasonable 4 digit value with 1 decimal point (for example, 755.5).



SET BAROMETRIC PRESSURE

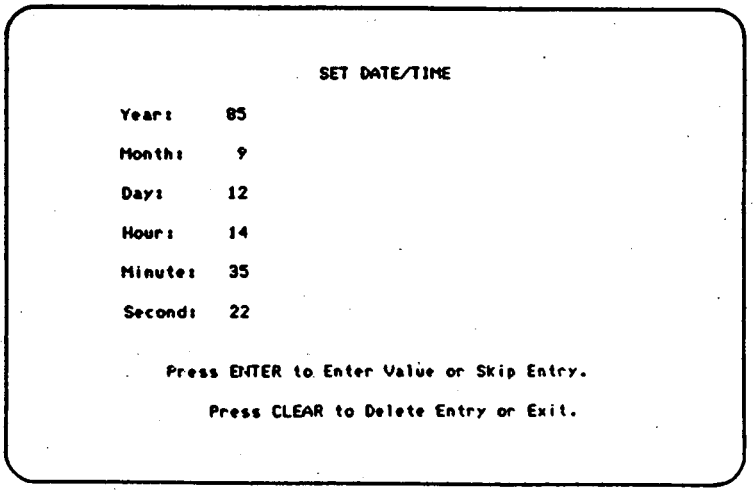
NOTE: The entered external barometric pressure must be between 450 to 800 mm Hg, 17 to 32 in. Hg, or 60 to 107 kPa. When the reported units of measurement are changed, the system automatically converts the barometer reading to match these units.

3. Press ENTER, setting the analyzer barometer to the external barometric pressure value.
4. Press CLEAR to return to the OPERATION MENU screen.

3.2.4 Set Date/Time

The Stat Profile 1 contains an internal 24 hour clock and calender. When the analyzer is powered up, the date is set to the release date of the program and the clock starts at 00:00:00. Set the date and time as follows.

1. Press 4, accessing the SET DATE/TIME screen.
2. Press ENTER repeatedly to move the cursor through the available parameters to the desired parameter.
3. Key in the new date or time value you wish to enter.



SET DATE/TIME

NOTE: Entering any value except seconds will "freeze" the clock. To start the clock again, enter a seconds value. This allows you to synchronize the analyzer's clock with another clock.

4. Press ENTER to replace the original value with the new value. To cancel an entry press CLEAR before pressing ENTER.
5. Repeat Steps 2 through 4 for all desired parameters.
6. Press CLEAR to return to the Operation Menu screen.

3.3 Calibration

3.3.1 Two-point Calibration (Automatic and Manual)

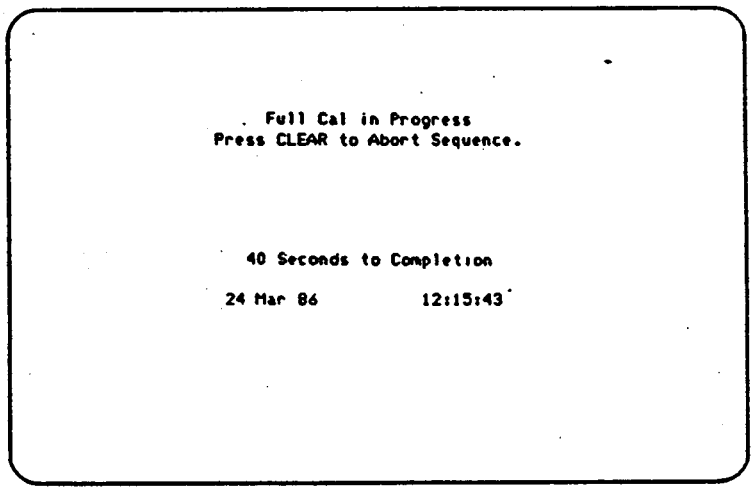
3.3.1.1 Automatic Calibration (Auto-Cal)

The analyzer performs an automatic two-point calibration, known as an autocalibration, 30 minutes after power up and at 2 hour intervals thereafter. If a sample is analyzed at the 2 hour point, autocalibration is delayed until 5 minutes after the sample has been analyzed. Autocalibration can be delayed in this way until 2 and 1/2 hours past the last calibration. When an autocalibration is performed, further sample analysis is disallowed.

3.3.1.2 Manual Calibration

A manual two-point calibration can be performed at any time by pressing CAL, ENTER. Manual calibration resets the autocalibration timer for 2 hour intervals from the time of the manual calibration.

To perform a manual calibration press CAL, ENTER. The CRT displays the Full Cal in Progress screen. To abort a manual calibration, press CLEAR.



Full Cal (Calibration) in Progress

3.3.2 Gas, pH/Hct, or Electrolyte Subsystem Calibrations

A two-point calibration of gas, pH and hematocrit, or electrolyte electrodes subsystems can be performed whenever you do not need calibration of all electrode subsystems. Subsystem calibrations are commonly performed when maintenance is performed on an electrode, when new reagents or gases have been introduced to the system, for electrode performance verification, or for troubleshooting information. For information on subsystem calibrations and other options available from the Maintenance Menu, see Section 5.1.

NOTE: Performing a Subsystem Calibration does not reset the autocalibration timer; only a full calibration resets the timer.

3.3.3 Aborting Calibrations

A calibration can be aborted to perform an emergency stat analysis. In this case, the previous calibration slopes are used for analysis calculations. The limitations to this procedure are as follows:

- The analyzer requires 30 seconds to prepare for an analysis after an aborted calibration. Since aborting a calibration with less than 30 seconds left would require more time than not aborting the calibration, the analyzer disallows aborting a calibration under this 30 second limit.

- An automatic two-point calibration cannot be aborted under any circumstance once a maximum of 2-1/2 hours has elapsed since the last two-point calibration was performed. This limitation is set to ensure that proper system performance is not compromised.

- At least 1 full calibration must have been completed in order to establish slope values for use in an abort procedure.

Abort a calibration as follows:

1. If the calibration progress screen is not displayed, press CLEAR repeatedly until it is displayed.
2. Press CLEAR, ENTER to initiate the abort sequence.

4 SAMPLE HANDLING

This section outlines sample handling requirements and gives reference values.

Correct sample handling is critical to ensure that the blood gas values obtained accurately reflect the "in vivo" state. Ensure that all samples have been obtained and stored following consistant, clinically accepted protocols. It is particularly important to ensure that samples are well mixed before introduction into the analyzer.

4.1 Acceptable Samples

Parameters	Sample(s)
pH*	Whole blood, plasma or serum
PCO_2 *	Whole blood, expired air
PO_2 *	Whole blood, expired air
Sodium	Whole blood, plasma or serum
Potassium	Whole blood, plasma or serum
Ionized Calcium*	Whole blood, plasma or serum
Hematocrit	Whole blood

*Anaerobic samples

Capillary Samples

Capillary sampling requires anticoagulated Natelson Capillary Tubes with an overall capacity of 280 ul. Adapt the Capillary Tubes to the instrument with NOVA Capillary Adapters (cat. no. 06529) as described in Capillary Sample Analysis, Section 3.1.2.

4.2 Anticoagulants

Sodium and lithium heparin are the recommended anticoagulants for pH, PCO_2, and PO_2. Other anticoagulants such as EDTA, citrate, oxalate, or sodium fluoride are not recommended for use with the instrument.

Depending on whether the pre-heparinized syringe or capillary is filled to capacity, blood containing anywhere from 20 I.U. per ml to over 100 I.U. per ml heparin will result. Sample containers that are not filled to capacity will have higher concentrations of heparin and may show inaccurate results due to the fact that sodium and lithium heparin will lower[1] ionized calcium results and sodium heparin may elevate[2] sodium results. (Our own experience indicates that 30 I.U. ml sodium heparin has no significant effect on sodium results.) Note these considerations when establishing reference intervals and interpreting values for these analytes.

4.3 Reference Values

Each laboratory should establish and maintain its own reference values. The values given here should be used only as a guide.

Table 4.1 Reference Values

Test	Arterial	Venous
pH	7.35-7.45	7.32-7.42
PCO_2	35-45 mmHg	41-51 mmHg
Actual Bicarbonate (plasma)	22-26 mmol/L	24-28 mmol/L
Standard Bicarbonate (plasma)	22-26 mmol/L	
Base Excess (blood)	0 ± 2	
Base Excess (extra cellular fluid)	0 ± 2	
PO_2		
(adults)	80-100 mmHg	25-40 mmHg
(over 65 years)	75-85 mmHg	
(infants)	60-70 mmHg	
O_2 Saturation	96-97%	40-70%
O_2 Content		
(Male)	17.5-23.0 Vol%	
(Female)	16.0-21.5 Vol%	
Hematocrit		
(Male)	43-51%	
(Female)	38-46%	

Test	Values for Whole Blood
Na	138-146 mmol/L
K	3.7-5.5 mmol/L
Ca^{++}	1.13-1.32 mmol/L

1. Determination of Blood Ionized Calcium in a Large Segment of the Normal Adult Population
Drop L. J., Fuchs, C., and Stulz P.M.
Clinica Chimica Acta 89, 503-510 (1978)

2. Collection and Preservation of Specimens
Winsten, S., Stand. Meth. Clin. Chem. 5, 1 (1965)

5 Maintenance

This section covers maintenance, describing the Maintenance Menu functions, outlining a schedule of maintenance, and describing the maintenance procedures. A list of recommended spare parts and supplies concludes the section.

A Maintenance Log (PN 06530), containing a performance record and a scheduled maintenance checklist, is supplied with the instrument. Use this log to record data for long-term performance verification and also to document instrument maintenance.

5.1 Maintenance Menu

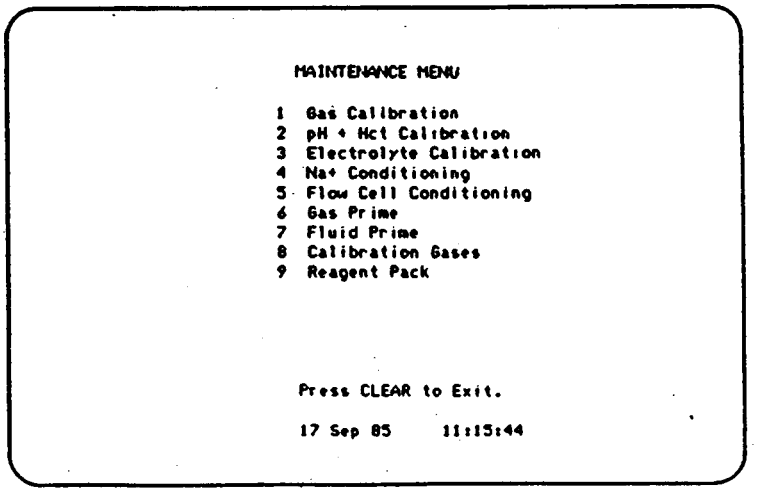
Access the Maintenance Menu functions to perform maintenance. The functions are:

- Electrode Subsystem Calibrations (Gas, pH + Hct, and Electrolytes) which save time over a complete system calibration
- Na^+ Conditioning for conditioning the sodium electrode
- Flow Cell Conditioning for conditioning the flow path with whole blood
- Gas and Fluid Primes for bringing gas or reagents into the system
- Set Calibration Gases for setting the calibration gas values
- Reagent Pack installation to enter the expected number of analyses

CAUTION: Subsystem two-point calibration cycles should not be aborted to perform a sample analysis. The subsystem two-point calibration slopes are erased when a subsystem calibration cycle begins.

Access the Maintenance Menu as follows:

1. From the Ready For Analysis screen, press MENU to access the Main Menu screen.
2. Press 2, accessing the Maintenance Menu screen. If the system is busy, access is disallowed until the system is idle.



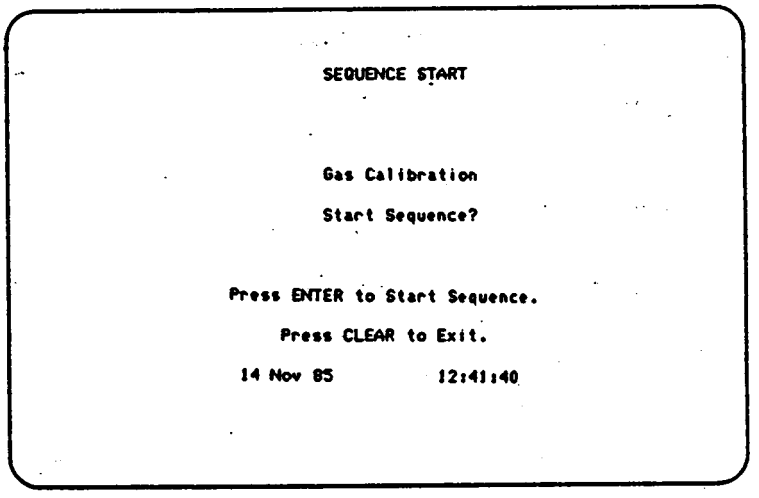
Maintenance Menu

3. See Sections 5.1.1 to 5.1.9 to access the appropriate maintenance screens. After accessing the desired screen, press ENTER (or ANALYZE for the Na^+ and Flow Cell conditioning functions) to begin the function. If, before pressing ENTER, you wish to exit any maintenance function, press CLEAR to return to the Maintenance Menu screen. Press CLEAR again to return to the Main Menu screen. Press CLEAR once more to return to Ready For Analysis screen.

5.1.1 Gas Calibration

Access this screen to do a PCO_2 and PO_2 gas electrodes subsystem two-point calibration. Start a gas calibration as follows:

1. Press 1 from the Maintenance Menu to access the gas calibration function. The Sequence Start screen is displayed.
2. Press ENTER to initiate a gas calibration. To abort a gas calibration, press CLEAR, ENTER.
3. After the calibration cycle is complete the Ready For Analysis screen is displayed.



Sequence Start (Gas)

If a gas electrode error occurs during calibration the operator will be alerted on the Ready For Analysis screen. If recalibration is not successful, troubleshoot per Section 6.2.

5.1.2 pH and Hct Calibration

Access this screen to do a pH and Hematocrit Impedance electrode subsystem two-point calibration. Start a pH and Hct calibration as follows:

1. Press 2 from the Maintenance Menu to access the pH and Hct calibration screen. The Sequence Start screen is displayed.
2. Press ENTER to initiate a pH and Hct calibration. To abort a pH and Hct calibration, press CLEAR, ENTER.
3. After the calibration cycle is complete, the Ready For Analysis screen is displayed.

If an error occurs during the calibration on either the pH electrode or the Hematocrit Impedance Electrode, you will be alerted on the Ready For Analysis screen. If recalibration is not successful, troubleshoot per Section 6.2.

5.1.3 Electrolyte Calibration

Access this screen to do a Na, K, and Ca^{++} electrode subsystem two-point calibration. Start an electrolyte calibration as follows:

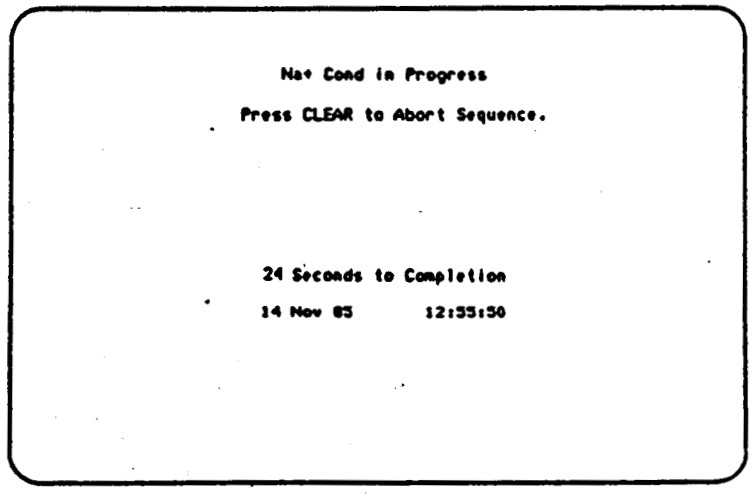
1. Press 3 from the Maintenance Menu to access the Electrolyte calibration screen. The Sequence Start screen is displayed.
2. Press ENTER to initiate an electrolyte calibration. To abort an electrolyte calibration, press CLEAR, ENTER.
3. After the calibration cycle is complete, the Ready For Analysis screen is displayed.

If an error occurs during the calibration on any electrolyte electrode, the operator will be alerted on the Ready For Analysis screen. If recalibration is not successful, troubleshoot per Section 6.2.

5.1.4 Na^+ Conditioning

This Section also appears in Section 5.4.2. Access this screen to condition the Na electrode. The instrument aspirates the Na conditioning solution to the Na electrode, conditions it for 30 seconds, then flushes the flow path. Condition the Na electrode as follows:

1. Fill a 2 ml sample cup 1/2 full of Na Conditioning Solution (PN 06856).
2. Press 4 from the Maintenance Menu, accessing the Position Sample screen and extending the probe.
3. Present the solution to the probe and press ANALYZE. After the probe retracts, the Na^+ Cond in Progress screen is displayed. To abort the cycle, press CLEAR, ENTER.
4. After completion of the cycle, the Ready For Analysis screen is displayed.



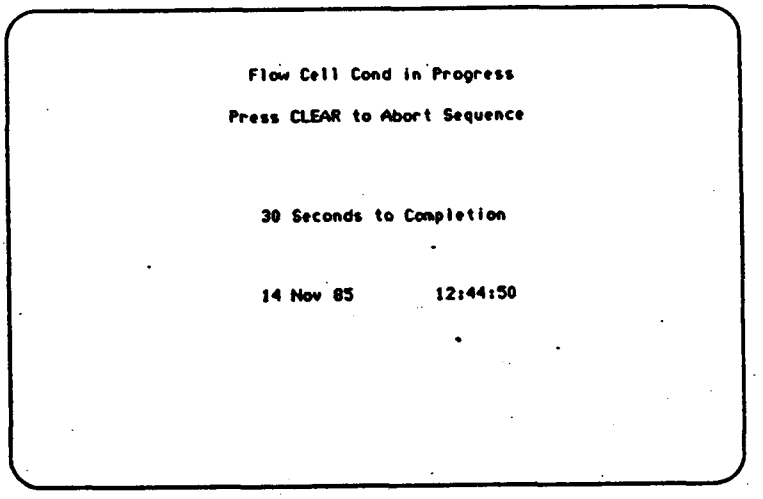
Na^+ Conditioning

5. Press CAL, ENTER to calibrate the instrument.
6. After the cycle is complete, the Ready For Analysis screen is displayed.

5.1.5 Flow Cell Conditioning

Access this screen to condition the flow cell with whole blood, thereby enhancing sample flow. The instrument aspirates blood into the flow cell, conditions for 5 minutes, then flushes the flow cell. Condition the flow cell as follows:

1. Fill a 2 ml sample cup 1/2 full of whole blood.
2. Press 5 from the Maintenance Menu, accessing the Position Sample screen and extending the probe.
3. Present the blood to the probe and press ANALYZE. After the probe retracts, the Flow Cell Cond in Progress screen is displayed. To abort the cycle, press CLEAR, ENTER.
4. After completion of the cycle, the Ready For Analysis screen is displayed.

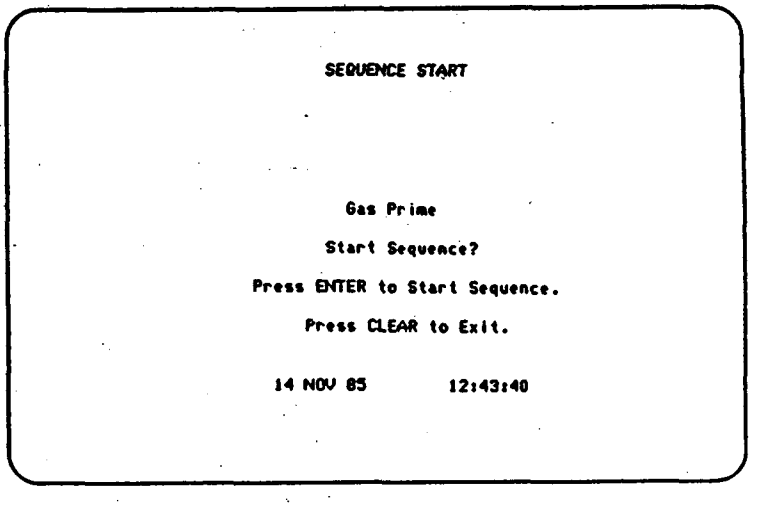


Flow Cell Conditioning

5.1.6 Gas Prime

Access this screen after changing the gas cylinders to prime the system with Gases A and B. Aborting a gas prime will cause a flush sequence to occur before the Ready For Analysis screen is displayed. Start a gas prime as follows:

1. Press 6 from the Maintenance Menu, accessing the Gas Prime Sequence Start screen.
2. Press ENTER to initiate a gas prime. To abort a gas prime press CLEAR, ENTER.
3. After completion of the gas prime, the Ready For Analysis screen is displayed.



Gas Prime Sequence Start

5.1.7 Fluid Prime

Access the fluid prime screen when changing the Reagent Pack and for other replacement and maintenance procedures. Aborting a fluid prime will cause a flush sequence to occur before the Ready For Analysis screen is displayed. Start a fluid prime as follows:

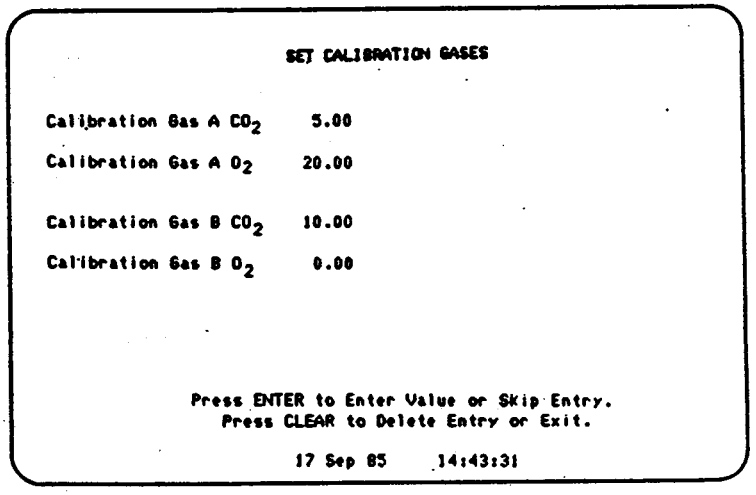
1. Press 7 from the Maintenance Menu, accessing the Fluid Prime Sequence Start screen.
2. Press ENTER to initiate a fluid prime. To abort a fluid prime press CLEAR, ENTER.
3. After completion of the fluid prime, the Ready For Analysis screen is displayed.

5.1.8 Set Calibration Gases

Access this screen to set the instrument program to match the gas cylinders gas percent composition values. Enter the gas percent composition into the the program as follows:

CAUTION: Correct calibration gas values are critical for valid calibration and analysis results.

1. From the Maintenance Menu, press 8 to access the Set Calibration Gases screen.
2. Press ENTER repeatedly to cycle the cursor (appearing to the right of the values) through the available values to the appropriate value.
3. Key in the correct percent gas composition value.
4. Press ENTER to replace the original value with the new default value. To cancel an entry, press CLEAR instead of pressing ENTER.



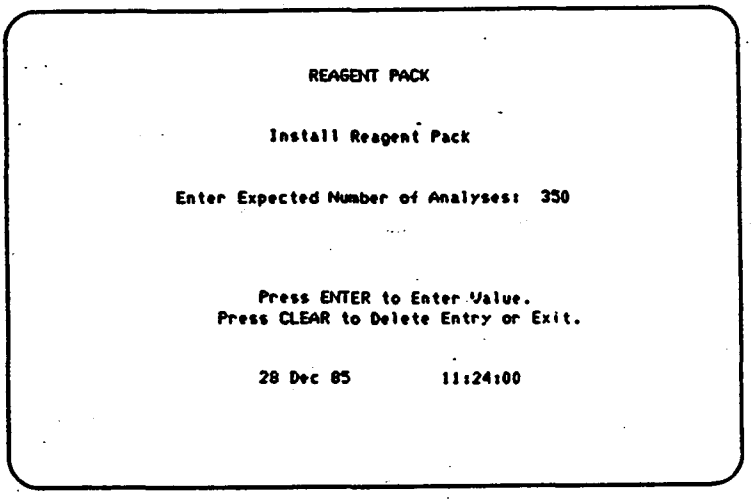
Set Calibration Gases

5. After all appropriate values have been changed, press CLEAR to return to the Maintenance Menu, then CLEAR again to return to the Main Menu, then CLEAR again to return to the Ready For Analysis screen.

5.1.9 Reagent Pack

The instrument monitors the expected number of analyses remaining in the reagent pack by counting down from an operator-set maximum number of analyses. This maximum number depends on the use rate of the specific lab and is determined on a trial basis by setting a number then adjusting this number when the reagent pack is replaced. (Replace the pack per Section 5.4.11 when the fluid in the window on the reagent pack is low and the instrument does not function due to low fluid levels.) The analyses remaining number is only an aid to externally monitor reagent pack fluid levels--instrument operation will not stop when 0 is reached. Start up a new reagent pack as follows:

1. Press 9, accessing the Reagent Pack screen.
2. Remove the old reagent pack per Section 5.4.12.
3. Install the new reagent pack in the reagent pack bay to the left of the analyzer compartment.
4. Enter the expected number of analyses (a 3 digit number), then press ENTER to enter the value. The Maintenance Menu screen is automatically displayed.
5. Perform a fluid prime per Section 5.1.7.



Reagent Pack

5.2 Performance Verification Data

For long-term performance verification, enter the following data daily in the performance record section of the Maintenance Log.

- System Status Values
  Flow times
  Air Bath and Sample Preheater Temperature
  Barometric Pressure difference from external barometer
  Tests Remaining in the Reagent Pack

- Electrode Slopes

- Standard A (pH), Standard C (Na, K, Ca^{++}), and Gas A (PCO_2, PO_2) millivolt values.

- NOVA Stat Profile Control Values
  (including Hematocrit Controls)

5.3 Scheduled Maintenance

It is extremely important to perform preventive maintenance as scheduled. The maintenance schedule is based on a 25 sample per day average. High volume labs should perform maintenance more frequently.

NOTE: Keep the analyzer compartment door closed as much as possible when performing maintenance. This will keep the components inside the analyzer compartment at the correct temperature and minimize the time needed to regain correct operating temperature.

Table 5.1 Scheduled Preventive Maintenance

	Section	Daily	Monthly	3 Months	6 Months	Yearly
Aspirate Cleaning Solution*	5.4.1	X				
Na^+ Conditioning Solution	5.4.2	X				
Flow Cell Conditioning w/Whole Blood**	5.4.3	X				
Clean Septum Assembly Inlet Port	5.4.4	X				
Check Humidifier Water Level	5.4.5	X				
Check Amt. and Pressure of Gases	5.4.23	X				
Remembrane Gas Electrodes	5.4.8, 9		X			
Replace W/R Tubing Segments	5.4.11		X			
Replace/Vacuum Fan Filter	5.4.22			X		
Replace W/R Harness	5.4.12				X	
Replace Reagent Harness	5.4.13				X	
Replace Septum Harness	5.4.14					X

*Most commonly performed at end of shift or day.

**Condition with whole blood after periods of instrument inactivity, cleaning, or electrode maintenance.

5.4 Maintenance Procedures

Perform these procedures per the suggested schedule in Section 5.3 and as needed. Check off procedure performance in the checklist contained in the maintenance log.

> CAUTION: In the following procedures, whenever the sampler probe is in position 9 (full extension) do not open or close the analyzer compartment door. Probe damage will occur if the door is opened or closed.

5.4.1 Aspirate Cleaning Solution (Flow Path Cleaning)

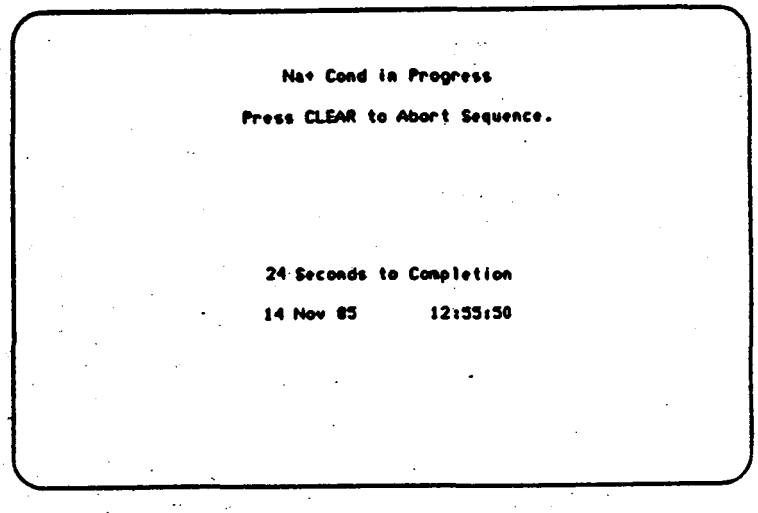
Aspirate cleaning solution to clean the flow path as follows:

1. Fill a 2 ml sample cup 1/2 full of cleaning solution (PN 06979).
2. From the Ready For Analysis screen, press MENU, 2, 5 to access the Position Sample screen of the Flow Cell Conditioning cycle.
3. Present the Cleaning Solution sample to the probe and press ANALYZE. After the probe retracts, the Flow Cell Cond in Progress screen is displayed (see Section 5.1.5). To abort the cycle, press CLEAR, ENTER.
4. After completion of the cycle, the Ready For Analysis screen is displayed.
5. Press CAL, ENTER to initiate a calibration. After the cycle is complete, press CAL, ENTER again for a second calibration.

5.4.2 Na^+ Conditioning

Access this screen to condition the Na electrode. The instrument aspirates the Na conditioning solution to the Na electrode, conditions it for 30 seconds, then flushes the flow path. Condition the Na electrode as follows:

1. Fill a 2 ml sample cup 1/4 full of Na Conditioning Solution (PN 06856).
2. From the Ready For Analysis screen, Press MENU, 2, 4 to access the Position Sample screen and extend the probe.
3. Present the solution to the probe and press ANALYZE. After the probe retracts, the Na^+ Cond in Progress screen is displayed. To abort the cycle, press CLEAR, ENTER.
4. After completion of the cycle, the Ready For Analysis screen is displayed.



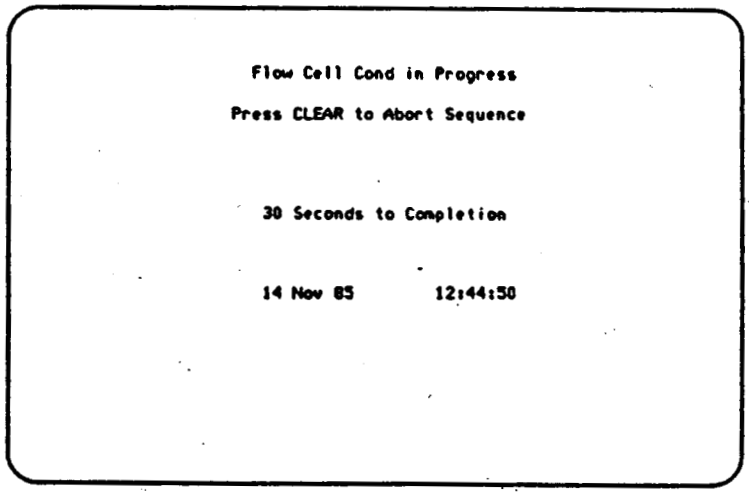
Na^+ Conditioning

5. Press CAL, ENTER to calibrate the instrument.
6. After the cycle is complete, the Ready For Analysis screen is displayed.

5.4.3 Flow Cell Conditioning

Condition the flow cell with whole blood to enhance sample flow. The instrument aspirates blood into the flow cell, conditions for 5 minutes, then flushes the flow cell. Condition the flow cell as follows:

1. Fill a 2 ml sample cup 1/2 full of whole blood.
2. From the Ready For Analysis screen, press MENU, 2, 5 to access the Position Sample screen and extend the probe.
3. Present the blood to the probe and press ANALYZE. After the probe retracts, the Flow Cell Cond in Progress screen is displayed. To abort the cycle, press CLEAR, ENTER.
4. After completion of the cycle, the Ready For Analysis screen is displayed.



Flow Cell Conditioning

5.4.4 Septum Assembly Inlet Port Cleaning

Whenever necessary, clean the septum assembly inlet port using a clean swab moistened with deionized water (Figure 5.1).

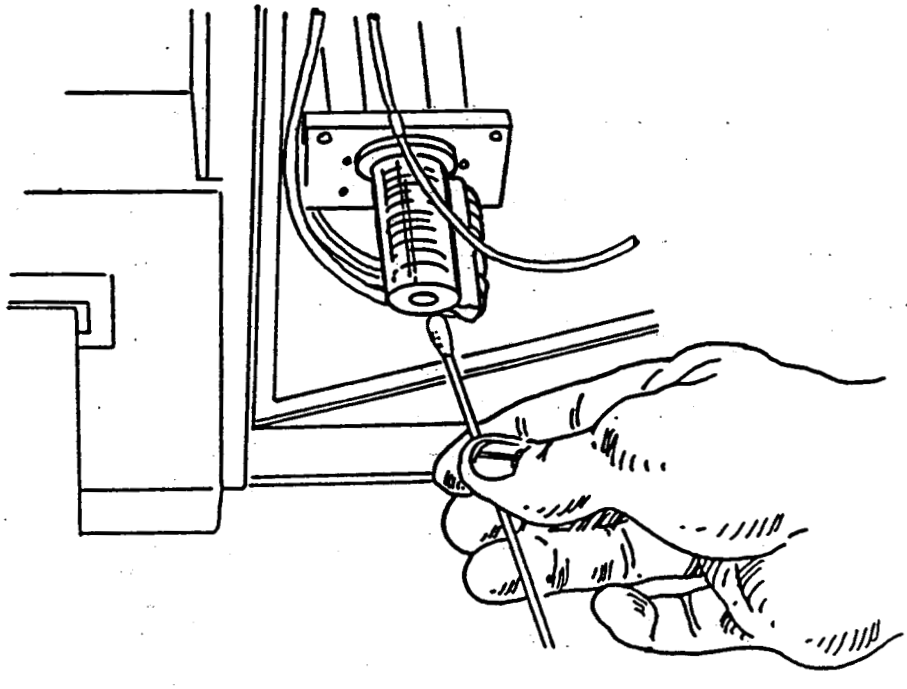


Figure 5.1 Septum Assembly Inlet Port Cleaning

5.4.5 Gas Humidifier Well Filling

Fill the humidifier chambers with deionized water to the fill lines on the chamber (Figure 5.2). When replacing the caps, ensure that they are correctly seated and tightened down fully to prevent gas leakage.

If over time the water becomes cloudy, withdraw the water with a syringe, rinse the chambers with deionized water, withdraw the rinse water, clean the chamber walls with a swab, then refill the chambers.

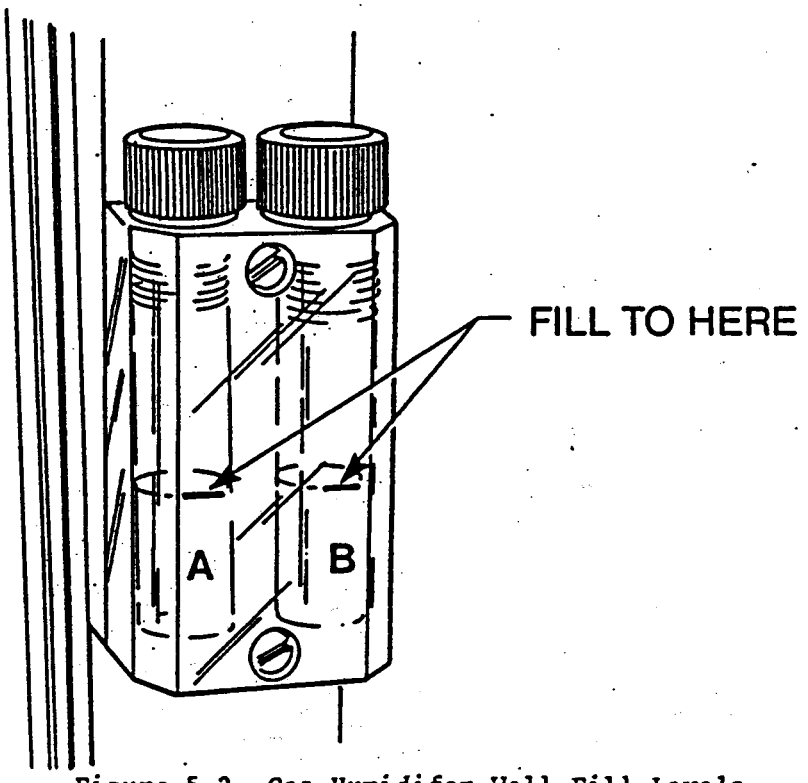


Figure 5.2 Gas Humidifer Well Fill Levels

5.4.6 Flow Path and Component Flushing

To flush the entire flow path with air or water, perform Steps 1 - 6 of the Flow Path Flush procedure. For a flush of the flow path starting at the sample preheater, open the analyzer compartment door, detach the crimp lock and S line from the sample preheater, attach the probe cleaning syringe tubing directly to the bottom of the sample preheater, access the System Test 1 screen, and continue with Step 4. When through with the procedure, reattach the S line and crimp lock to the sample preheater.

For individual components of the flow path, perform the appropriate procedure per the Individual Component procedures.

> CAUTION: Do not open or close the analyzer compartment door when the probe is in position 9. Probe damage will occur.

Flow Path Flush

1. Open the analyzer compartment door.
2. From the Ready For Analysis screen, press MENU, 3, 1, 6, 9 to move the sampler probe to the sample aspiration position.
3. Pull back on the plunger of a probe cleaning syringe (PN 02702) fitted with a length of tubing and attach the tubing to the sampler probe tip.
4. Press 9 to open the Pump Bypass Valve.
5. Push air through the flow path (Figure 5.3). If a flow blockage is encountered and not eliminated, perform the following flushing procedures for the suspected component.

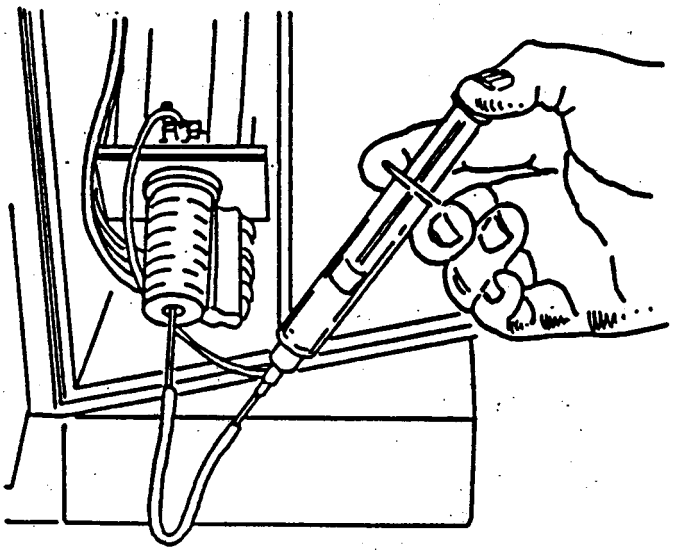


Figure 5.3 Flow Path Air Flush

6. If other components need flushing, continue with the Individual Component Flush as follows. If no other components need flushing, press 9, 6, 0, CLEAR, CLEAR to return to the Main Menu, and close the analyzer compartment door.

Individual Component Flush

Sampler Probe Flush

Check the probe for blockage and flush if necessary as follows:

1. Press 3, 1, 3 to change the PO_2 gain to Low. (Do this to delay automatic flush or calibration cycles for maintenance -- movement of any System Test function will result in delay of the cycles, but the PO_2 gain is the most convenient.)
2. Open the analyzer compartment door. Remove the S line from the sample preheater by sliding the black crimp lock off the sample preheater connector and pulling the S line off. Attach the flexible tubing of a syringe filled with deionized water to the S line.
3. From the Ready For Analysis screen, press MENU, 3, 1, 6, 9 to move the sampler probe out of the septum assembly. Position a beaker underneath the probe tip.
4. Push the deionized water through the probe.
5. If little or no flow occurs there is probably a blood clot in the sampler probe which may be freed by forcing deionized water through the probe. If this is not successful, draw some cleaning solution (PN 06979) into the syringe and, after letting the solution sit on the clot, force the remaining solution through the clot. Again attach a deionized water-filled syringe to the probe and push water through the probe.
6. If, after performing Step 5, a steady stream of water does not leave the probe tip, remove the probe (Section 5.4.16) and inspect for a bent sampler probe. A bent probe will reduce flow and should be replaced.
7. If no other components need flushing, press 3, CLEAR, CLEAR to return to the Main Menu, and close the analyzer compartment door.

Preheater, Flow Cell, and Reference Electrode Flush

Perform Steps 1 - 10, then proceed to the appropriate component(s). Refer to Figure 5.4 throughout this procedure.

1. From the Ready For Analysis screen, press MENU, 3, 1, 9, 8, 6 to empty the reagent lines.
2. After 10 seconds, press 8, 0, 9 to stop gas flow.
3. Press 3 to change the PO_2 gain to Low. (Do this to delay automatic flush or calibration cycles for maintenance -- movement of any System Test function will result in delay of the cycles, but the PO_2 gain is the most convenient.)
4. Clamp and disconnect the W and R lines from the reference electrode.
5. Unplug all electrode cables from the electrode rack assembly.
6. Disconnect the S line from the sampler preheater by sliding the crimp lock off the connector and pulling the S line off.

7. Remove the preheater-flow cell-reference electrode assembly by first turning the bottom slotted retainer screw 1/4 turn counterclockwise, then pulling the assembly straight off the guide pin and electrical connectors.
8. Loosen the thumbscrew located on top of the reference electrode, turn the retaining block to the side, and retighten the thumbscrew.
9. Lift the reference electrode up and out of the way of the flow cell.
10. If the blocked component is known, proceed to the component as follows. Otherwise, continue with Step 11.

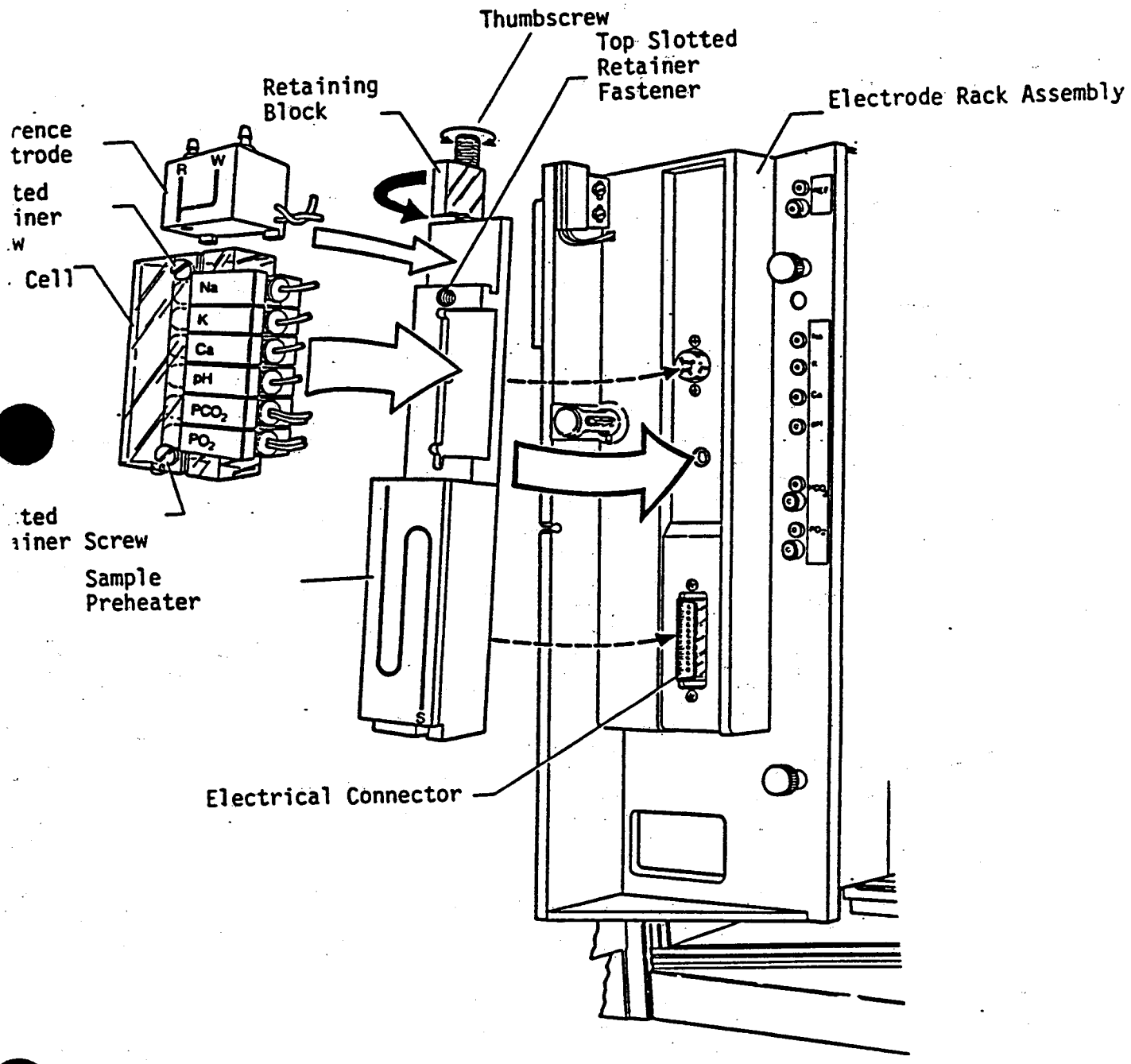
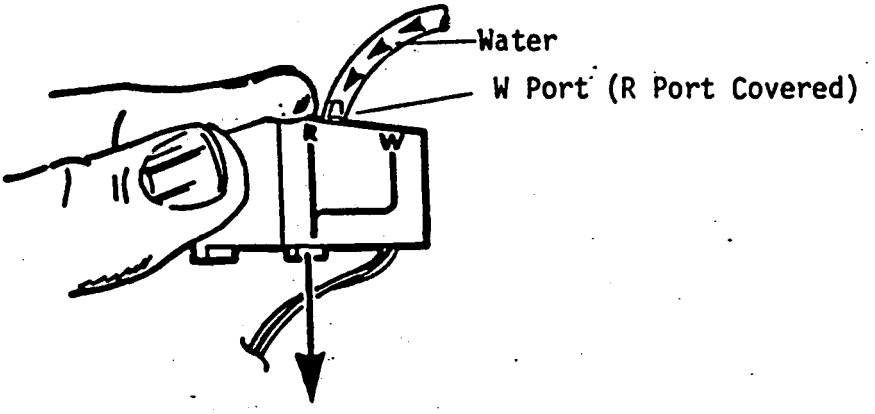


Figure 5.4 Preheater-Flow Cell-Reference Installation

Reference Electrode Flush

11. Attach a syringe containing deionized water to W port (Figure 5.5) and, while covering the R port, push water through the electrode so that the water flows out the flow cell port.



5.5 Flushing the Reference Electrode

12. Repeat Step 11, attaching the syringe to the R port and covering the W port.
13. If flushing the flow cell or the sample preheater is not needed, continue with Step 22. Otherwise, turn the top thumbscrew 1/4 turn counter-clockwise and lift the flow cell with the electrodes still inserted off the sample preheater connector. Continue with the appropriate component.

Flow Cell Flush

14. Insert the blunt tip needle (from probe cleaning kit) of a syringe filled with deionized water into an interconnect tubing on the flow cell and push deionized water through the flow cell (Figure 5.6).

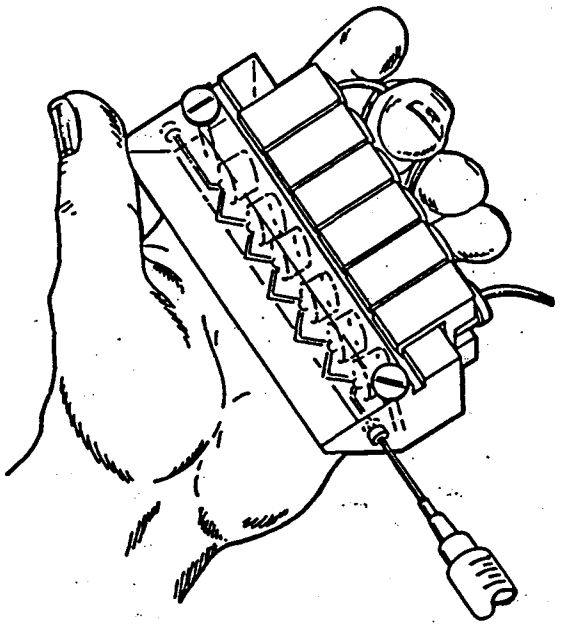


Figure 5.6 Flushing the Flow Cell

15. Repeat Step 14, flushing the flow cell in the opposite direction by holding the syringe onto the other flow cell interconnect tubing.
16. Inspect the flow cell for cracks and other physical damage.
17. Check the interconnect tubing attached to the flow cell for leaks or breakage.

Sample Preheater Flush

18. If the flow cell is still on the sample preheater, remove by turning the top slotted retainer screw 1/4 turn counter-clockwise.
19. Attach the tubing of a cleaning syringe filled with deionized water to the bottom connector and push water through the sample preheater (Figure 5.7).

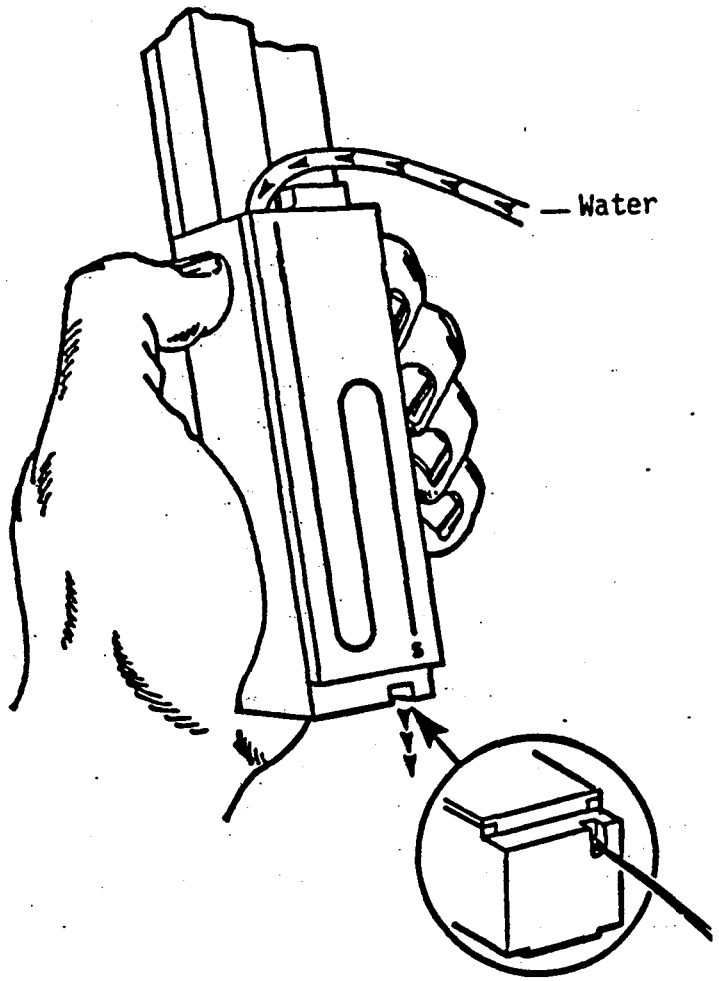


Figure 5.7 Flushing the Sample Preheater

20. For best cleaning, repeat Step 19, pushing water through the top connector of the preheater.

Reassembly Procedure

21. Reattach the flow cell to the sample preheater back plate as follows:

    a. Set the flow cell into the recess on the sample preheater, aligning the right surface of the flow cell flush with the right side of the back plate. Ensure that the flow cell interconnect tubing is seated properly on the sample preheater top connector.
    b. Turn the top slotted retainer screw 1/4 turn clockwise.

22. Replace the reference electrode on top of the flow cell by placing the electrode on top of the flow cell, aligning the electrode sides with the backplate sides. Ensure that the reference electrode connector is seated properly on the flow cell interconnect tubing.

23. Loosen the retaining block thumbscrew, center the retaining block in the depression on top of the electrode, and retighten the thumbscrew.
24. Replace the preheater-flow cell-reference electrode assembly by aligning the guide pin, pressing the assembly onto the electrical connectors, then turning the bottom slotted retainer screw 1/4 turn clockwise to engage the electrode rack assembly.
25. Plug all cables into the electrode rack assembly.
26. Reconnect the S line to the sample preheater by connecting the S line and sliding the crimp lock over the connection.
27. Attach and unclamp the W and R lines to the reference electrode.
28. Close the analyzer compartment door and wait 5 minutes for the compartment to come to temperature.
29. Verify good flow of solution as follows:

    a. Press 6, 1, 5, 4 to aspirate flush solution.
    b. Observe the waste line for proper flow for 5 seconds. Stop aspiration by pressing 5, 0. If the flow was impeded, check the interconnections between the S line - preheater, preheater - flow cell, and flow cell - reference electrode, and check that the W and R tubings are properly connected.

30. Press 6, 0, CLEAR, CLEAR, CLEAR, to return to the Ready for Analysis screen.
31. Press CAL, ENTER to perform a two-point calibration.

5.4.7 Na, K, Ca^{++}, and pH Electrode Preconditioning and Replacement

1. From the Ready For Analysis screen, press MENU, 3, 1, 9, 8, 6 to manually prime gas and displace fluid from the flow cell.
2. After 10 seconds, press 8, 0, 9 to stop the gas prime.
3. Press 3 to change the PO_2 gain to Low. (Do this to delay automatic flush or calibration cycles for maintenance -- movement of any System Test function will result in delay of the cycles, but the PO_2 gain is the most convenient.)
4. Open the analyzer compartment door and locate the electrode to be replaced. If removing the Na electrode, using extra care to avoid damaging the electrode.
5. Unplug the electrode cable from the electrode rack assembly.
6. Unclip the electrode and remove from the flow cell (Figure 5.8).

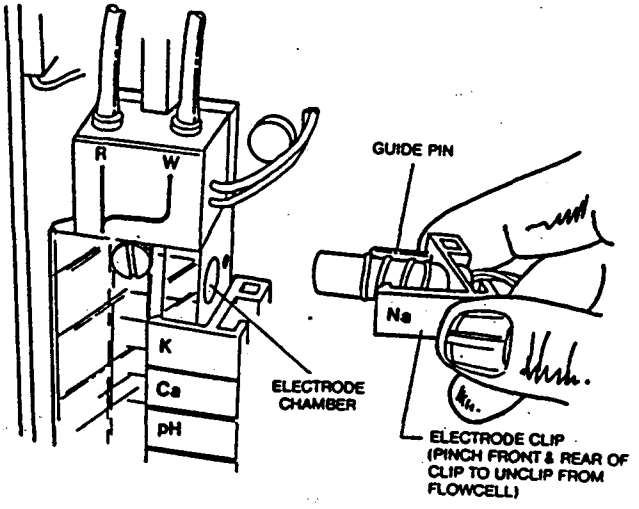


Figure 5.8 Electrode-Flow Cell Assembly

7. Remove the washer using the washer removal tool (PN 07157 - hook the washer with the hook end of the tool) and, with a lintless tissue or swab, dry the electrode chamber and washer thoroughly. If bubble hang up at the electrode tip was a problem, or if other problems suggest a bad washer, replace the washer per Step 8. The sodium chamber does not contain a washer.
8. Position the correct electrode washer (from kit PN 07159) on the broad end of the washer removal tool (Figure 5.9) and insert it into the flow cell, seating it against the back wall of the chamber. If washer replacement is the only action needed (conditioning the electrode is unnecessary), perform the following:

    a. Insert the electrode into the flow cell by sliding the guide pin and electrode body into the flow cell until it clips into place.
    b. Plug the cable into the electrode rack assembly.
    c. Go to Step 11.

9. Close the analyzer compartment door.

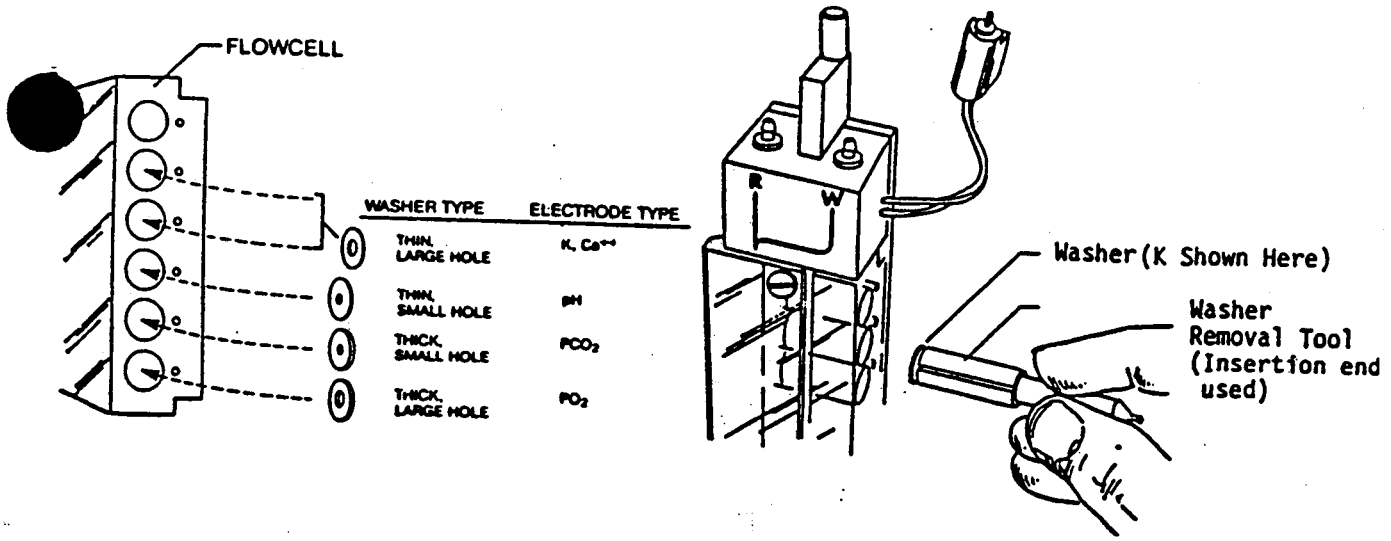


Figure 5.9 Flow Cell Washers and Insertion

10. Precondition the Na, K, Ca^{++}, or pH electrode as follows:

Sodium

> CAUTION: The sodium electrode is extremely delicate; handle with extra care to avoid damage.

a. Open the analyzer compartment door. Insert the electrode (PN 06011) into the flow cell by sliding the guide pin and electrode body into the flow cell until it clips into place.
b. Plug in the cable.
c. Close the analyzer compartment door.
d. Fill a 2 ml sample cup with Na Conditioning solution (PN 06856).

NOTE: All electrodes must be in the flow cell during a Na Conditioning cycle.

e. Press CLEAR, CLEAR to return to the Main Menu screen, then press 2, 4 and present the solution to the probe.
f. Press ANALYZE to aspirate the solution. Withdraw the cup when the probe retracts.
g. When the cycle is finished, press MENU, 2, 4, then present the Na solution to the probe and press ANALYZE for a second Na conditioning cycle.
h. From the Ready For Analysis screen, press MENU, 2, 3, ENTER to perform an Electrolyte Calibration.
i. Repeat Step h, performing a second Electrolyte Calibration cycle.
j. If performing maintenance on other electrodes, press MENU, 3, 1, 3 to change the PO_2 gain to Low. (Do this to delay automatic flush or calibration cycles for maintenance -- movement of any System Test function will result in delay of the cycles, but the PO_2 gain is the most convenient.) Otherwise, go to Step 11.

Potassium and Ionized Calcium

a. Holding the electrode (K - PN 06009, Ca^{++} - PN 06007) tip downwards, with a wrist-snapping motion shake the electrode down to move air bubbles to the back of the electrode.
b. Open the analyzer compartment door.
c. Without raising the electrode tip above the horizontal (to avoid moving air bubbles back to the tip), insert the electrode into the flow cell chamber by sliding the guide pin and electrode body into the flow cell until the electrode clips into place.
d. Plug the cable into the electrode rack assembly.

pH

a. Fill a 2 ml sample cup 1/2 full with pH/PCO_2 Conditioning Solution (PN 06857).
b. Place the measuring end of the electrode (PN 06013) into the cup so that the tip of the electrode is immersed in the pH/PCO_2 Conditioning Solution.
c. Wait 5 minutes.
d. Remove the electrode from the cup and rinse with deionized water.
e. Dry the electrode with a lintless tissue, taking care to avoid touching the tip.
f. Open the analyzer compartment door.
g. Insert the electrode into the flow cell by sliding the guide pin and electrode body into the flow cell until the electrode clips into place.
h. Plug the cable into the electrode rack assembly.

11. Close the analyzer compartment door.
12. Press CLEAR, CLEAR, CLEAR to return to the Ready for Analysis screen.
13. Condition with whole blood as follows (see also Section 5.4.3):

NOTE: All electrodes must be in the flow cell during a Flow Cell Conditioning cycle.

a. Fill a 2 ml sample cup 1/2 full of whole blood.
b. From the Ready For Analysis screen, press MENU, 2, 5 and present the blood to the probe.
c. Press ANALYZE to aspirate the blood. Withdraw the cup when the probe retracts.

14. Perform a subsystem calibration to verify electrode performance. If the sodium, potassium, or ionized calcium electrodes were replaced, press MENU, 2, 3, ENTER to initiate an Electrolyte calibration. If the pH electrode was replaced, press MENU, 2, 2, ENTER to initiate a pH + Hct Electrode calibration.
15. If desired, press CAL, ENTER to perform a two-point calibration.

5.4.8 PCO_2 Electrode Conditioning, Membraning and Replacement

This procedure is for the new-style PCO_2 electrode (PN 07541). Refer to the alternate procedure located in the addendum at the back of the manual if your electrode is old-style (identifiable by the vent hole located midway along the sleeve).

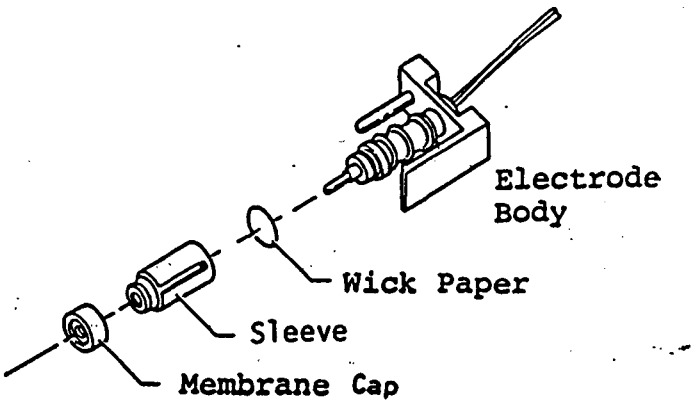


Figure 5.10 PCO_2 Electrode Assembly

1. From the Ready For Analysis screen, press MENU, 3, 1, 9, 8, 6 to manually prime gas and displace fluid from the Flow Cell.
2. After 10 seconds, press 8, 0, 9 to stop the gas prime.
3. Press 3 to change the PO_2 gain to Low. (Do this to delay automatic flush or calibration cycles for maintenance -- movement of any System Test function will result in delay of the cycles, but the PO_2 gain is the most convenient.)
4. Open the analyzer compartment door.
5. Unplug the electrode cable from the electrode rack assembly.
6. Remove the PCO_2 electrode (PN 07541) by pinching the front and rear of the electrode clip and sliding out of the flow cell.
7. Remove the PCO_2 washer using the washer removal tool (PN 07157 - hook the washer with the hook end of the tool). With a lintless tissue or swab, dry the electrode chamber and washer throroughly. If bubble hang up at the electrode tip was a problem, or if other problems suggest a bad washer, replace the washer (from kit PN 07159) and continue with Step 8; otherwise, reuse the washer in Step 8.
8. Position the thick, small-hole washer on the broad end of the washer removal tool (Figure 5.11). Align the groove on the washer removal tool with the flow cell alignment pin, and insert the tool into the flow cell, seating the washer against the back wall of the chamber. If membraning the electrode is unnecessary, go to Step 26 to replace the electrode in the flow cell.

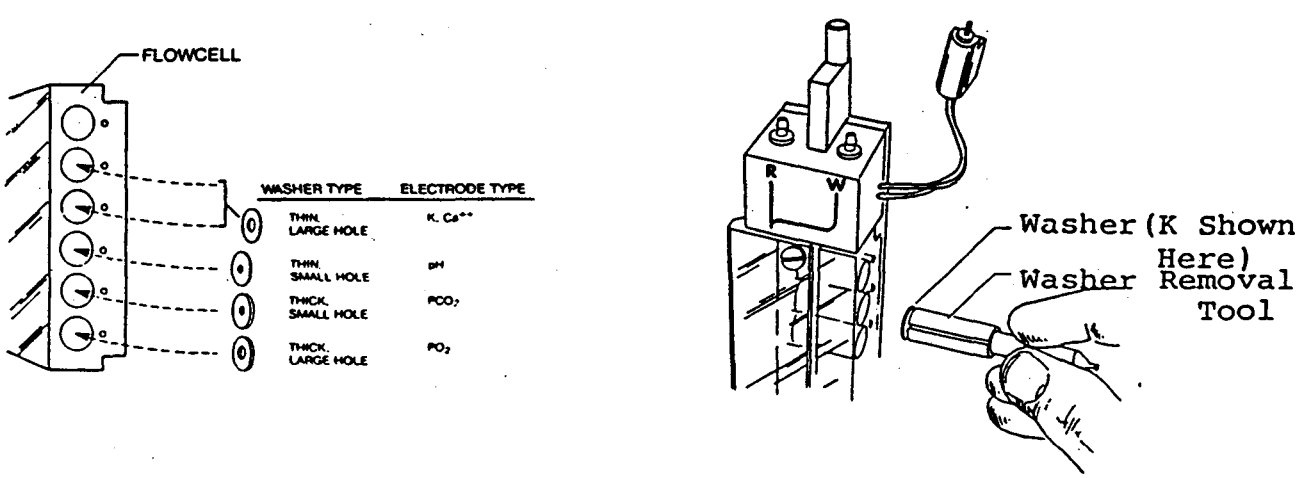


Figure 5.11 Flow Cell Washers and Insertion

Update Listing - Stat Profile 1 Instruction Manual, Rev B

New Steps for PCO_2 Electrode Procedure, Section 5.4.8

The following steps update this instruction manual for the new PCO_2 electrode sleeve. Perform these steps instead of the steps in the manual. Do not use the old-style PCO_2 procedure located in the addendum bound in the back of the manual.

Note the new Figure 5.10, showing the new location of the sleeve vent hole (changed from the back of the groove to midway along the sleeve).

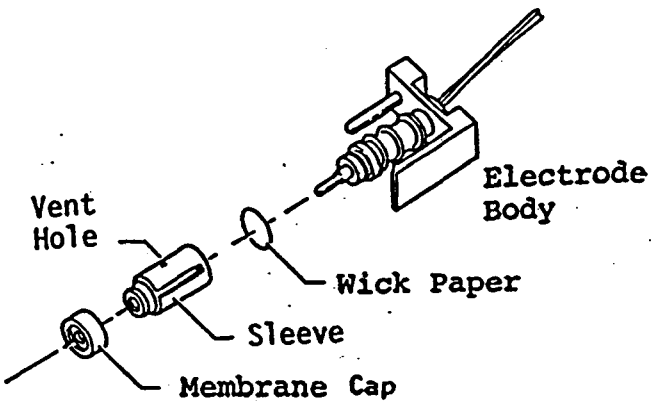


Figure 5.10 PCO_2 Electrode Assembly

Step	Replace with:
21.	Fill the sleeve/cap to the vent hole with PCO_2 electrolyte solution (not the fill line as shown in Figure 5.15).
22.	Insert the electrode body into the sleeve/cap, pressing down firmly to ensure a good seal (Figure 5.16). A small amount of electrolyte solution may squirt out the vent hole. If this happens, dry the outside of the sleeve thoroughly with a lintless tissue or swab. Do not touch the measuring surface of the membrane. When the electrode is held horizontally, a bubble extending almost the length of the sleeve will be seen. This bubble is necessary for thermal expansion of the electrolyte solution after the electrode is inserted in the flow cell.
23.	a. Hold the electrode with the cap downward and with a thumb over the fill hole. With a wrist-snapping motion, shake the electrode down to move air bubbles to the back of the electrode.

Step	Replace with:
27.	a. Wait 15 minutes for the electrode to come to temperature. b. Perform a PCO_2 Membrane Test (Section 6.3.1.3), but, if the test is positive, do not immediately remembrane the electrode. Instead, do the following: • Remove the electrode and washer and dry the washer, electrode, and chamber thoroughly with a lintless tissue or swab. • Replace the electrode and washer in the instrument. • Repeat the test. If the test is again positive, remembrane the electrode. c. If an error code 83, PCO_2 MEM OVERLOAD occurs during normal operation, suspect a leak from the vent hole. Solve the error as follows: • Remove the electrode and washer and dry the washer, electrode, and chamber thoroughly with a lintless tissue or swab. • Replace the electrode and washer in the instrument. • Perform a PCO_2 Membrane Test (Section 6.3.1.3). If the test is positive, remembrane the electrode.

9. Close the analyzer compartment door.

> CAUTION: Do not wiggle or twist the electrode body or sleeve when assembling or taking apart the electrode; slide the cap straight on or off in one quick motion to avoid damaging the glass tip.

10. Remove the PCO_2 sleeve/cap unit from the electrode body by carefully pulling it straight off.
11. Remove and discard the old membrane cap and wick paper from the sleeve.
12. If the electrode is new, or if you are performing a troubleshooting procedure, condition the electrode as follows. Otherwise, continue with Step 13.

    a. Fill a 2 ml sample cup 1/2 full with pH/PCO_2 conditioning solution (PN 06857).
    b. Replace the sleeve on the electrode body (to protect the glass tip).
    c. Place the sleeve end of the electrode into the sample cup so that the tip of the electrode is immersed in the pH/PCO_2 conditioning solution.
    d. Condition for 15 minutes.
    e. Remove the electrode body from the cup, remove the sleeve, and rinse the sleeve and electrode tip with deionized water.
    f. Dry the electrode tip and the sleeve with a lintless tissue.

NOTE: When assembling the electrode in the following steps, touch the membrane cap on the edges only; avoid contact with the measuring surface of the membrane cap.

13. Fit the membrane cap (From Kit PN 07543) on the sleeve by hooking one edge of the membrane cap onto the rim of the sleeve and working the cap over the sleeve rim (Figure 5.12). Be careful not to touch the cap measuring surface during this procedure.

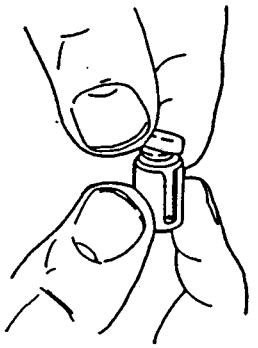


Figure 5.12 Sleeve-Cap Installation

14. Put 3 drops of PCO_2 electrolyte solution (PN 06553) into the inverted sleeve/cap.
15. Tap the sleeve/cap with a finger to dislodge any trapped bubbles.
16. Place the PCO_2 wick insertion tool (PN 07542) base onto a clean work surface.
17. Place the sleeve/cap into the base, cap end first (Figure 5.13).

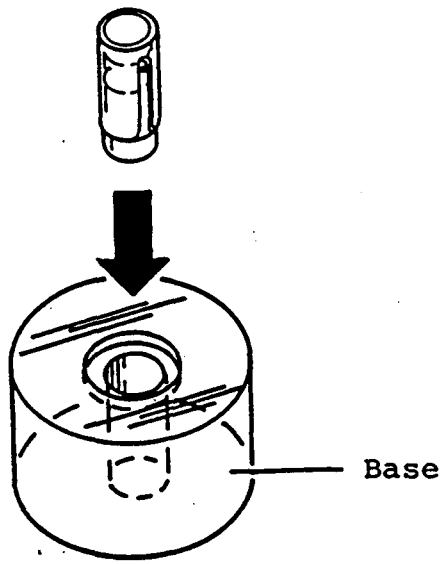


Figure 5.13 Insert Sleeve/Cap In Base

18. Separate the wick paper (From Kit PN 07543) away from the card and place into the indentation on the base.
19. Center the inserter over the wick paper, and insert it into the base, pressing the wick paper into the sleeve (Figure 5.14). Withdraw the inserter.

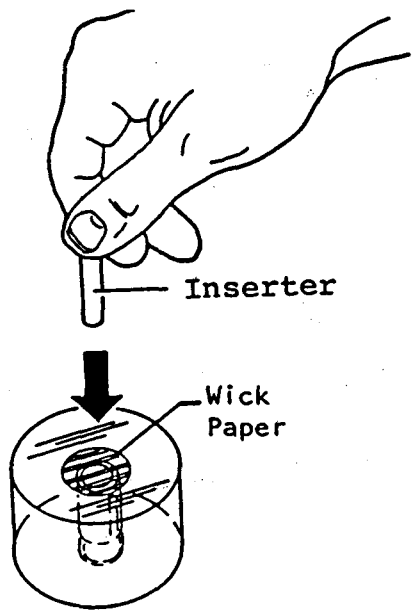


Figure 5.14 Inserting The Wick Paper Into The Sleeve

20. Remove the base, leaving the sleeve/cap on the work surface.
21. Fill the sleeve/cap to the fill line with PCO_2 electrolyte solution. The fill line is located about 1/3 of the way from the back end (Figure 5.15).

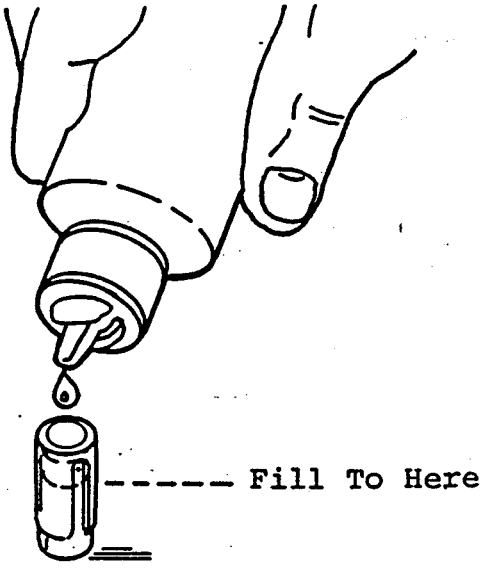


Figure 5.15 Fill Sleeve/Cap To Fill Line

> **CAUTION:** In the following step, do not wiggle or twist the electrode body or sleeve/cap when assembling the electrode; slide the cap straight on in <u>one quick motion</u> to avoid damaging the glass tip.

22. Insert the electrode body into the sleeve/cap, pressing down firmly to ensure a good seal (Figure 5.16).

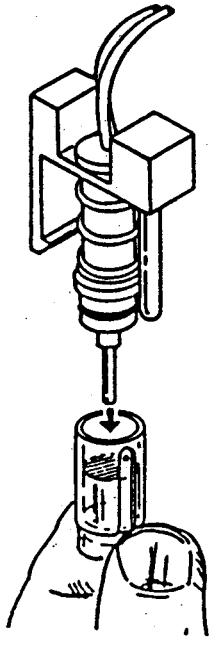


Figure 5.16 Electrode-Sleeve/Cap Insertion

23. Degas the electrode as follows:

    a. Hold the electrode with the cap downward. With a wrist-snapping motion, shake the electrode down to move air bubbles to the back of the electrode.
    b. With the electrode tip still downward, observe the tip for bubbles. If bubbles are present, tap the electrode with a finger to loosen the bubbles and again shake the electrode down. Repeat if necessary.

24. Dry the electrode with a lintless tissue. Do not touch the surface of the membrane.
25. Open the analyzer compartment door.
26. Insert the electrode into the flow cell by aligning the groove on the sleeve so that it is aligned with the flow cell chamber alignment pin (Figure 5.17). Next, insert the electrode guide pin and electrode body into the flow cell, clipping the electrode into place. Plug the cable into the electrode rack assembly. Close the analyzer compartment door.

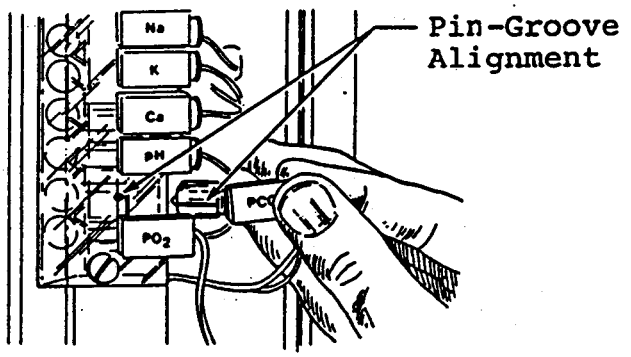


Figure 5.17 PCO_2 Electrode-Flow Cell Alignment

27. Wait 15 minutes for the electrode to come to temperature.
28. Press CLEAR, CLEAR, CLEAR to return to the Ready for Analysis screen.
29. Condition with whole blood as follows:

    NOTE: All electrodes must be in the flow cell during a Flow Cell Conditioning cycle.

    a. Fill a 2 ml sample cup 1/2 full of whole blood.
    b. From the Ready For Analysis screen, press MENU, 2, 5 and present the blood to the probe.
    c. Press ANALYZE to aspirate the blood. Withdraw the cup when the probe retracts.

30. After completion of the conditioning cycle, press MENU, 2, 1, ENTER, initiating a gas calibration to verify electrode performance. If the electrode does not calibrate due to slope errors, remove air bubbles as follows:

    a. Displace fluid from the flow cell and remove the electrode per Steps 1 - 9.
    b. Degas the electrode per Step 23. Do not add more electrolyte solution.
    c. Open the analyzer compartment door, and reinsert the electrode into the flow cell per Step 26.
    d. Press MENU, 2, 1, ENTER, again initiating a gas calibration to verify electrode performance.

5.4.9 PO_2 Electrode Conditioning, Membraning, and Replacement

The following procedure explains how to membrane the electrode and how to polish the PO_2 electrode (polishing should be performed when the slope performance number goes below -5).

1. From the Ready For Analysis screen, press MENU, 3, 1, 9, 8, 6 to manually prime gas and displace fluid from the flow cell.
2. After 10 seconds, press 8, 0, 9 to stop the gas prime.
3. Press 3 to change the PO_2 gain to Low. (Do this to delay automatic flush or calibration cycles for maintenance -- movement of any System Test function will result in delay of the cycles, but the PO_2 gain is the most convenient.)
4. Open the analyzer compartment door.
5. Unplug the electrode cable from the electrode rack assembly.
6. Unclip the PO_2 electrode (PN 06015) and remove from the flow cell (Figure 5.18).

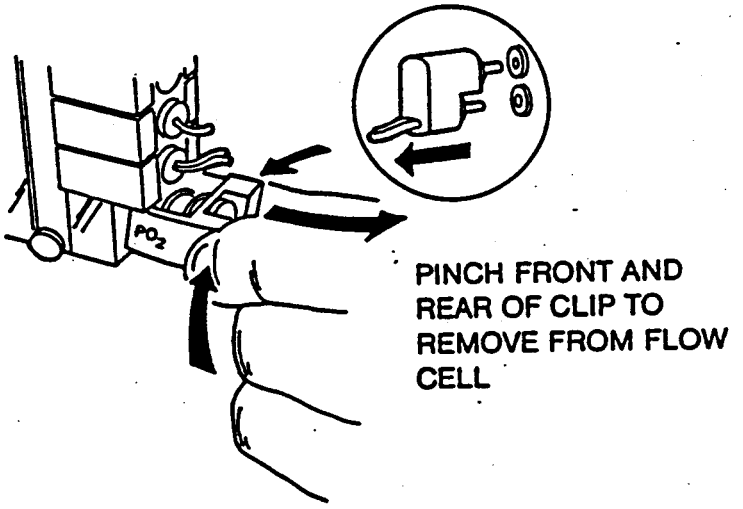


Figure 5.18 PO_2 Electrode Removal

7. Remove the PO_2 washer using the washer removal tool (PN 07157 - hook the washer with the hook end of the tool). Dry the flow cell chamber and washer with a lintless tissue or swab. If bubble hang up at the electrode tip was a problem, or if other problems suggest a bad washer, replace the washer (from kit PN 07159) and continue with Step 8; otherwise, reuse the washer in Step 8.
8. Position the thick, large-hole washer on the broad end of the washer removal tool and insert it into the flow cell, seating it against the back wall of the chamber (Figure 5.19). If membraning the electrode is unnecessary, go to Step 23 to replace the electrode in the flow cell.

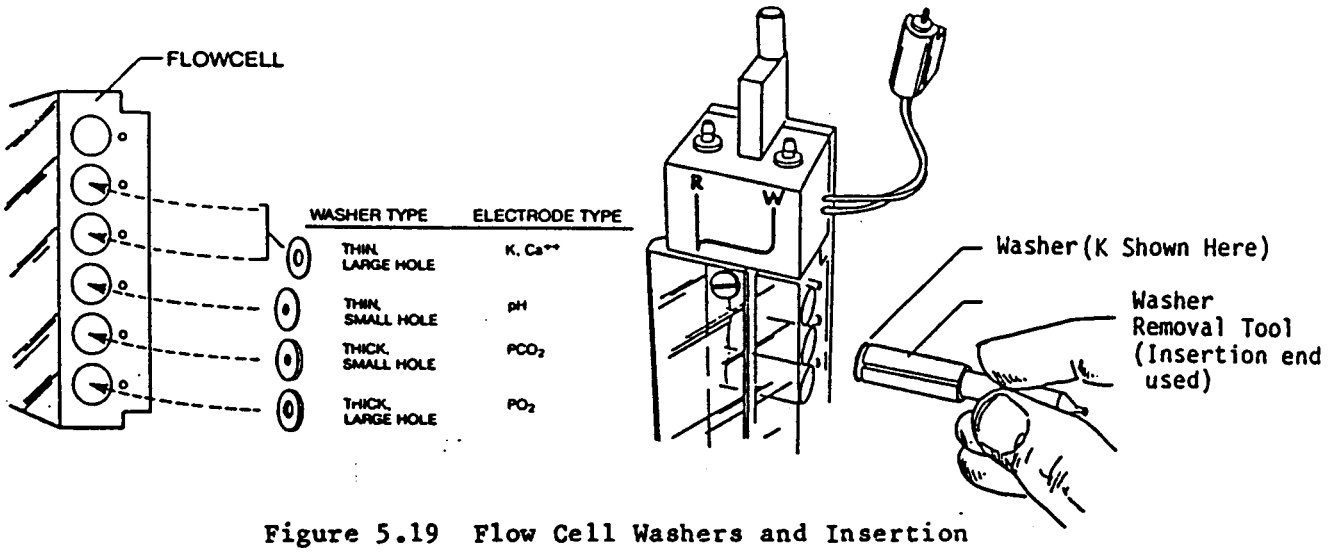


Figure 5.19 Flow Cell Washers and Insertion

9. Close the analyzer compartment door.
10. Prepare the Application Tools (PN 06532) as follows:

    a. Place an O-ring (From Kit PN 06569) onto the tapered end of the white cone and slide the O-ring down midway onto the cylindrical end of the tool. The O-ring will stretch (Figure 5.20a).
    b. Drop the cone into the application tool base, pointed end first. The cylindrical end of the cone tool will protrude above the base (Figure 5.20b).
    c. Place the new membrane (from kit PN 06569) print side down into the inverted application tool cover (The membrane print will be up when the cover is placed onto the tool base - Figure 5.20c).
    d. Press the application tool cover with membrane down onto the application tool base. The cone tool will be pressed into the base (Figure 5.20d).

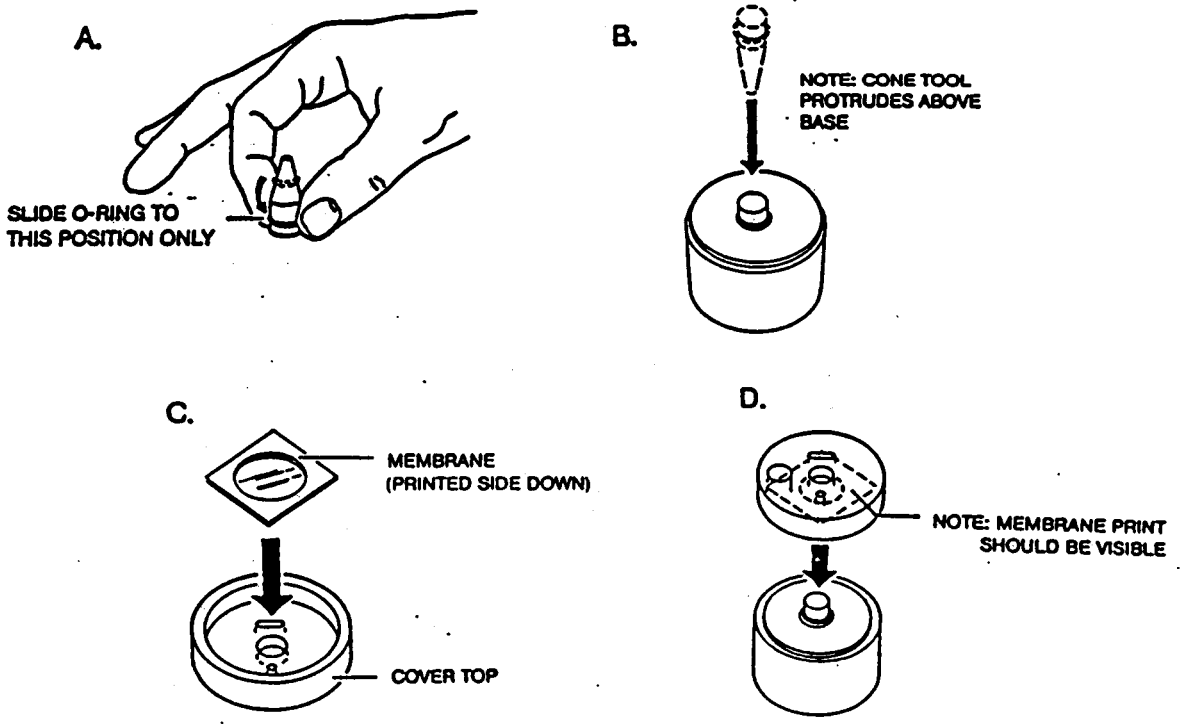


Figure 5.20 Membraning Tool Preparation

11. Remove the old membrane and O-ring from the tip of the electrode by grasping the membrane edge and pulling off.
12. Shake the electrode down to remove the old electrolyte solution.
13. If the electrode is being membraned because of a low slope performance number (less than -5), polish the electrode as follows; otherwise, continue with Step 14.

    a. Place a drop of PO_2 electrolyte solution (PN 06554) on the polishing paper (from kit PN 06569).
    b. Hold the PO_2 polishing paper so that the tip of your index finger provides some pressure against the back of the paper (Figure 5.21).
    c. Gently polish the electrode tip on the paper, moving the tip in a circular fashion for about 10 seconds.

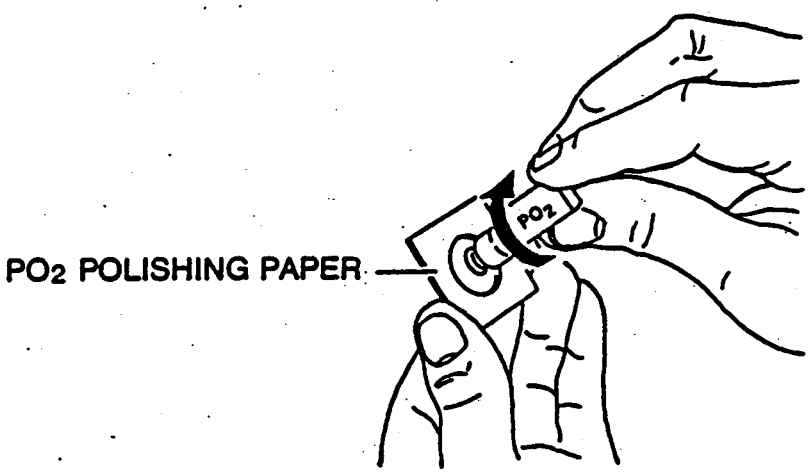


Figure 5.21 PO_2 Electrode Tip Polishing

14. Wipe the electrode tip with lintless tissue soaked in PO_2 Electrolyte Solution (Figure 5.22). Dry the tip, ensuring that the fill holes are clear of liquid.

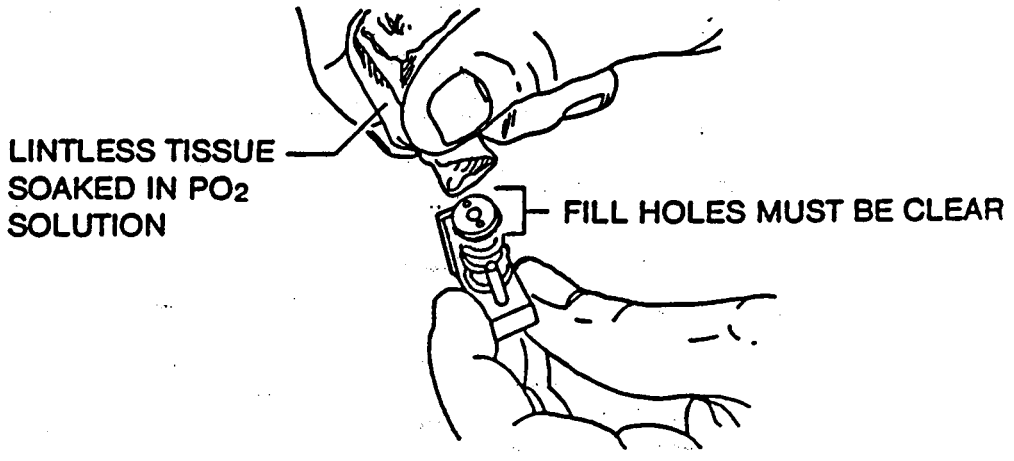


Figure 5.22 Electrode Tip Wiping

15. Fill a syringe body with fresh PO_2 Electrolyte Solution (PN 06554). Attach the probe tip.
16. Fill the electrode, holding it at a 45° angle with the tip up and the syringe tip inserted into the bottommost fill hole (Figure 5.23). The Electrolyte Solution will displace air out of the second fill hole, allowing complete filling of the electrode. If the electrode does not fill easily, clear the second fill hole of liquid by drying with a lintless tissue or swab.

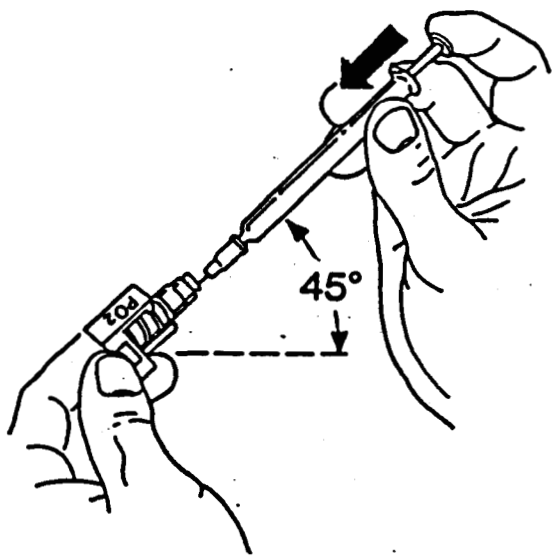


Figure 5.23 PO_2 Electrode Filling

17. Insert the electrode into the application tool, using the alignment slots on the application tool cover. Using your thumbs, press down on the backside of the clip and guide pin until the membrane and O-ring snap onto the electrode body (Figure 5.24).

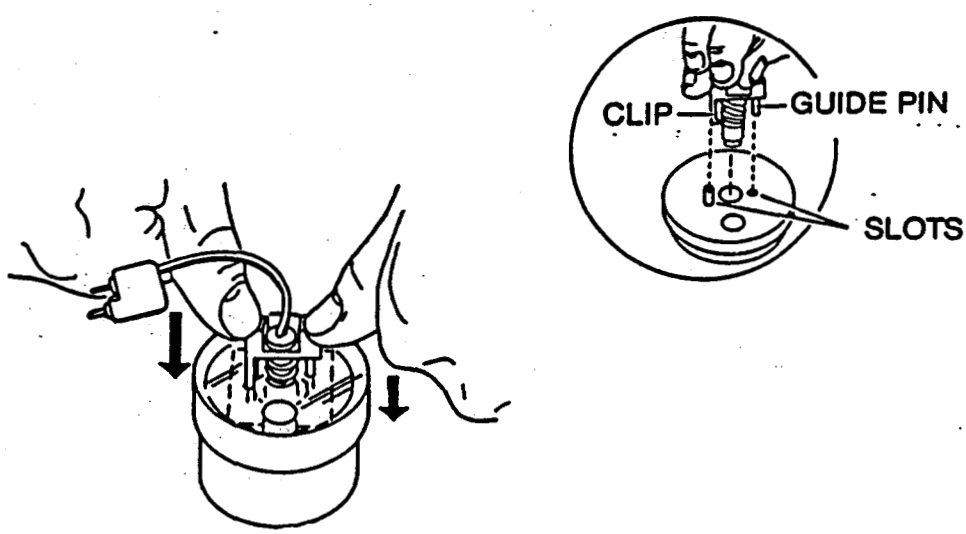


Figure 5.24 Inserting Electrode Into Membraning Tool

18. Withdraw the electrode from the application tool.
19. Inspect both the electrode and membrane, ensuring that there are no wrinkles or tears and that the O-ring has seated itself in the groove on the electrode tip.
20. Dry the body of the electrode.
21. Open the analyzer compartment door.
22. Remove bubbles from the electrode membrane as follows:

    a. Holding the electrode with the tip downward, with a wrist-snapping motion shake the electrode down to move air bubbles to the back of the electrode.
    b. With the electrode tip still downward, observe the tip for bubbles. If bubbles are present, tap the electrode with a finger to loosen the bubbles and again shake the electrode down. Repeat if necessary.
    c. Proceed to Step 23, keeping the electrode tip below the horizontal (to avoid moving air bubbles to the tip).

23. Replace the electrode by sliding the guide pin and electrode body into the flow cell until the electrode clips into place.
24. Plug the electrode cable into the electrode rack assembly.
25. Close the analyzer compartment door.
26. Press CLEAR, CLEAR, CLEAR to return to the Ready For Analysis screen.
27. Wait 15 minutes to allow the electrode to come to instrument temperature.
28. Condition with whole blood as follows (see also Section 5.4.1):

    a. Fill a 2 ml sample cup with whole blood.

    NOTE: All electrodes must be in the flow cell during a Flow Cell Conditioning cycle.

    b. From the Ready For Analysis screen, press MENU, 2, 5 and present the blood to the probe.
    c. Press ANALYZE to aspirate the blood. Withdraw the cup when the probe retracts.

29. After completion of the conditioning cycle, press MENU, 2, 1, ENTER, initiating a gas calibration to verify electrode performance. If the electrode does not calibrate due to slope errors, remove air bubbles as follows:

    a. Open the analyzer compartment door, remove the electrode, unplug the cable, and degas per Step 22. Do not add more Electrolyte solution.
    b. Reinsert the electrode into the flow cell, plug the electrode cable into electrode rack assembly, and close the analyzer compartment door.
    c. Press MENU, 2, 1, ENTER, again initiating a gas calibration to verify electrode performance.

5.4.10 Reference Electrode Replacement

1. From the Ready For Analysis screen, press MENU, 3, 1 to access the System Test screen.
2. Press 3 to change the PO_2 gain to Low. (Do this to delay automatic flush or calibration cycles for maintenance -- movement of any System Test function will result in delay of the cycles, but the PO_2 gain is the most convenient.)
3. Open the analyzer compartment door.
4. Clamp and disconnect the W and R lines from the reference electrode.
5. Unplug the reference electrode cable from the electrode rack assembly.
6. Loosen the thumbscrew located on top of the reference electrode, turn the retaining block to the side, and retighten the thumbscrew (Figure 5.25).

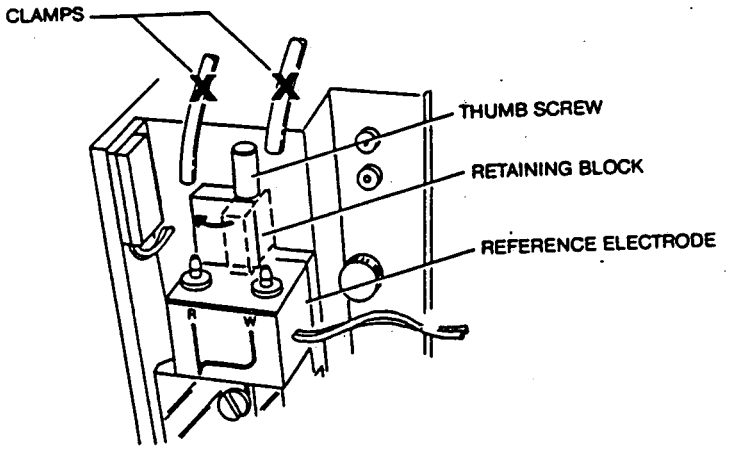


Figure 5.25 Reference Electrode Replacement

7. Lift the old reference electrode up and out of the way of the flow cell.
8. Place the new reference electrode (PN 06025) on top of the flow cell, aligning the electrode sides with the backplate sides. Ensure that the reference electrode connector is seated properly on the flow cell interconnect tubing.
9. Loosen the retaining block thumbscrew, center the retaining block in the depression on top of the electrode, and retighten the thumbscrew.
10. Plug the cable into the electrode rack assembly.
11. Attach and unclamp the W and R lines to the reference electrode.
12. Close the analyzer compartment door.
13. Press 3, CLEAR, CLEAR, CLEAR to return to the Ready For Analysis screen. If the instrument displays the Not Ready screen with the AIR BATH NOT READY status message, wait until the instrument reaches operating temperature and the Ready For Analysis screen is displayed.
14. Press CAL, ENTER to perform a two-point calibration. When the cycle is finished, press CAL, ENTER again for a second calibration.

C-3

5.4.11 W/R Tubing Segment Replacement

Tubing segments that go around the pump can be replaced without replacement of the complete W/R harness. The following procedure is for replacing these segments (done monthly). To replace the complete W/R harness (done every 6 months), see Section 5.4.12.

1. From the Ready For Analysis screen, press MENU, 3, 1, 3 to change the PO_2 gain to Low. (Do this to delay automatic flush or calibration cycles for maintenance -- movement of any System Test function will result in delay of the cycles, but the PO_2 gain is the most convenient.)
2. Open the plexiglass cover, exposing the fluids deck.
3. Press 9 to open the pump bypass valve. Remove the W bypass tubing segment from the pump bypass valve (Figure 5.26).

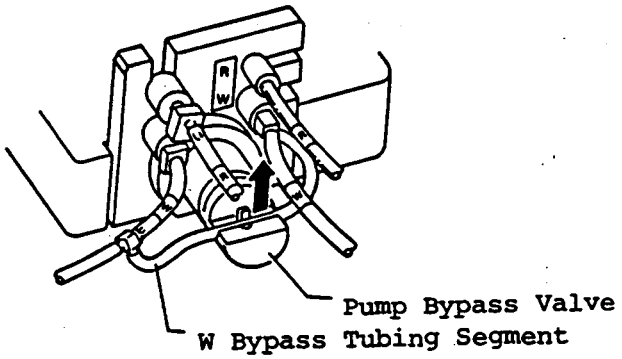


Figure 5.26 W Bypass Tubing Segment Removal

4. Remove the pump segments from the pump as follows:

   a. Stretch outward and lift the R and W tubing collars from the horizontal slots in the tubing support block (Figure 5.27).
   b. Remove the remaining tubing collars from the tubing support block. The pump segments are now free of the pump.

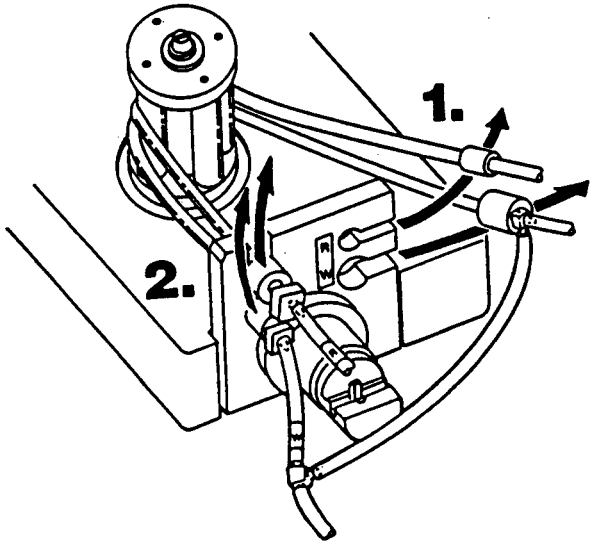


Figure 5.27 Pump Segment Removal

5. Disconnect the old W tubing segment as follows, referring to Figure 5.28:

   a. Disconnect the W bypass segment from the T connector located on the collar towards the rear of the instrument.
   b. Disconnect the front W tubing from the T connector closest to the front of the instrument. Disconnect the rear W tubing from the W pump tubing segment by pulling the tubing off at the collar. The W tubing segment (including the W bypass segment, T connector, pump segment, and small tubing) is now free of the instrument.

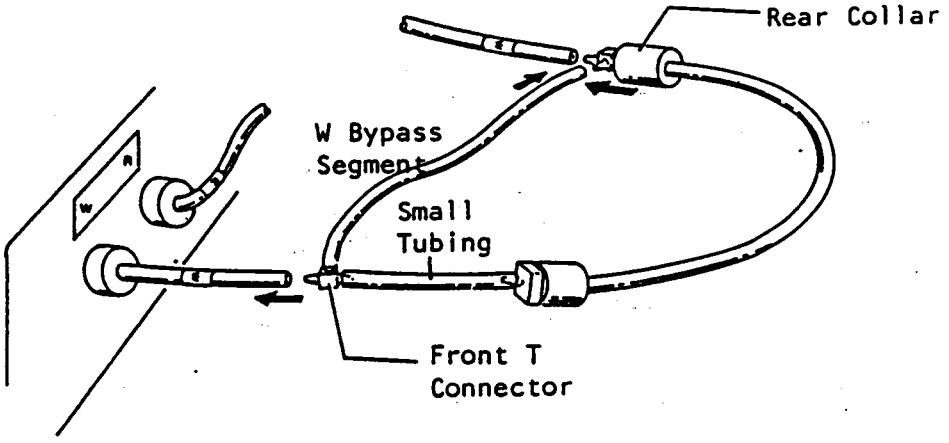


Figure 5.28 W Tubing Segment Removal

6. Disconnect the old R tubing segment as follows, referring to Figure 5.29:

   a. Pull the tubing segment off the segment connector located at the large collar.
   b. Open the analyzer compartment door.
   c. Pull the R tubing off the reference electrode.
   d. Pull the white plug out of the analyzer compartment opening.

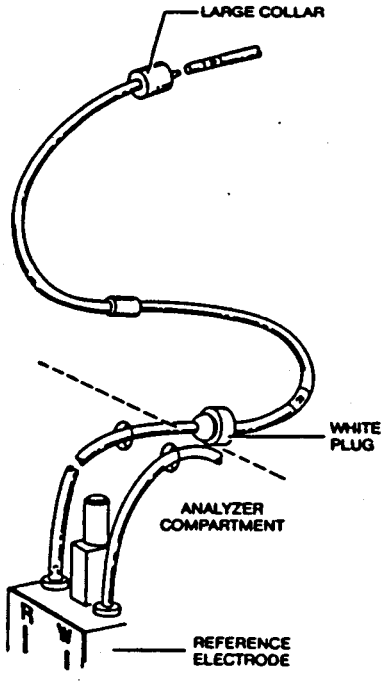


Figure 5.29 R Tubing Segment Removal

7. Remove any connectors that did not come off with the segments. Discard the old segments and connectors.
8. Insert the new W tubing segment into the harness as follows:

   a. Referring to Figure 5.30 for correct orientation, connect the front and rear of the W line of the W/R harness to the new W tubing segment (W/R Tubing Segments - PN 07501).
   b. Attach the free end of the W bypass tubing segment to the T connector on the rear collar.

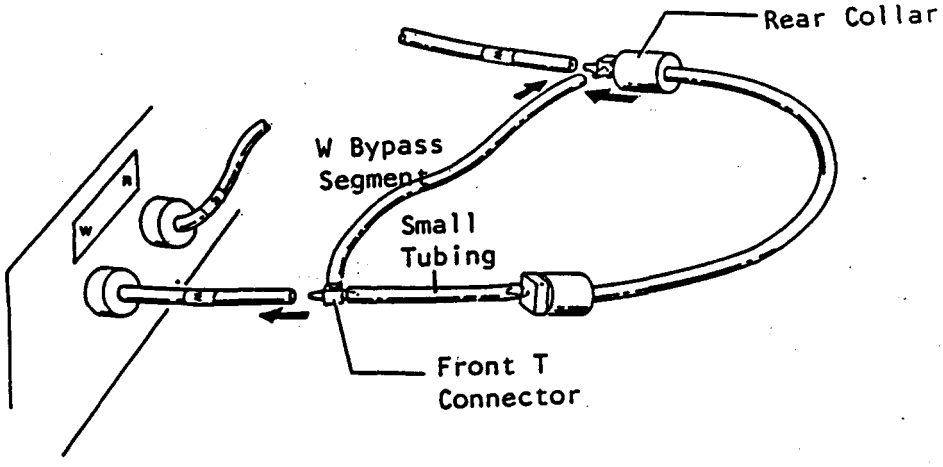


Figure 5.30 W Tubing Segment Replacement

9. Connect the new R tubing segment to the W/R harness as follows:

   a. Connect the tubing segment to the connector located at the large collar.
   b. Pull the R tubing off the reference electrode.
   c. Open the analyzer compartment door.
   d. Plug the white plug into the analyzer compartment opening.

10. Referring to Figure 5.31, install the new tubing segments as follows:

> CAUTION: Do not overstretch the pump segments in the steps that follow. Overstretched pump segments will give inadequate drawing pressure and will require replacement of the segment.

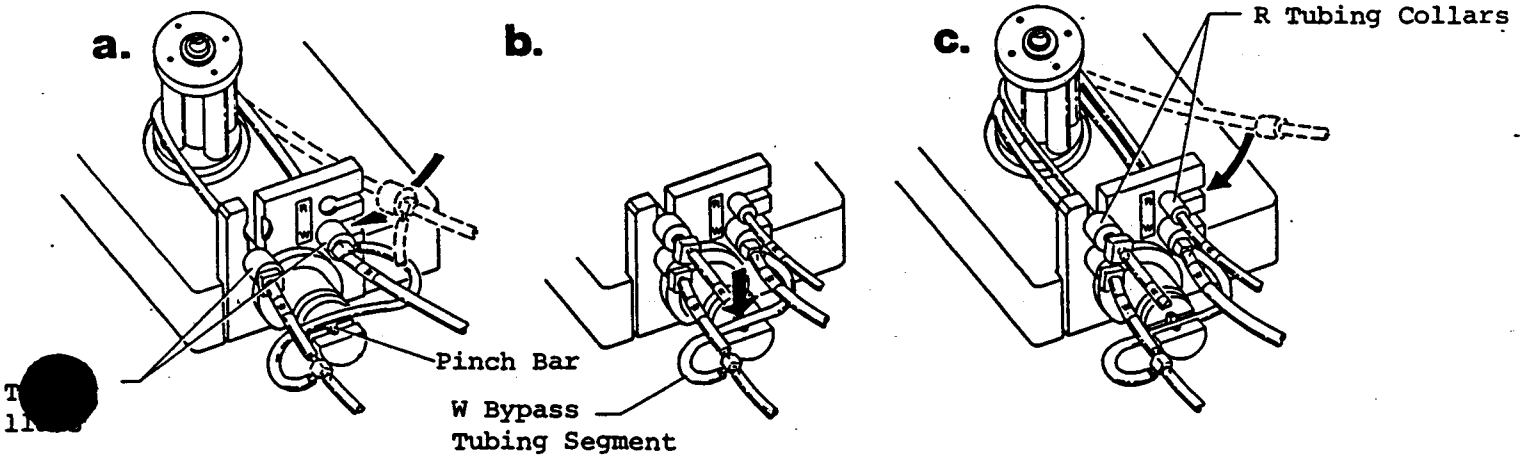


Figure 5.31 Tubing Segment Installation

a. Position the W pump segment of the new W/R harness around the lower portion of the pump assembly, stretching the tubing slightly so that the collar closest to the white plug fits into the front retainer slot and the collar closest to the reagent pack straw fits into the rear retainer slot.
b. Insert the W bypass tubing segment into the pump bypass valve by moving the pinch bar out of the way with a small screwdriver or fingernail, and placing the tubing segment in the valve.
c. Position the new R line around the upper portion of the pump assembly, stretching the tubing slightly so that the larger black collar fits into the front retainer slot and the smaller gray collar fits into the rear retainer slot.

11. Press 5, 4, 6, 1 to draw reference solution into the reference electrode.
12. When the fluid/air transition passes into the reference electrode (about 2 minutes), press 5, 0, 6, 0 to stop aspiration.
13. Press CLEAR, CLEAR, CLEAR to return to the Ready for Analysis screen.
14. Close the plexiglass cover.
15. Press CAL, ENTER to calibrate the instrument.

5.4.12 W/R Harness Replacement

Replace the complete W/R harness (including pump segments) as follows. To replace the pump segments only, refer to Section 5.4.11.

1. From the Ready For Analysis screen, press MENU, 3, 1, 3 to change the PO_2 gain to Low. (Do this to delay automatic flush or calibration cycles for maintenance -- movement of any System Test function will result in delay of the cycles, but the PO_2 gain is the most convenient.)
2. Open the plexiglass cover, exposing the fluids deck.
3. Open the analyzer compartment door and disconnect the R and W tubings from the reference electrode. Remove the white plugs holding the tubing in the compartment and remove the tubing from the compartment. Close the analyzer compartment door.
4. Press 9 to open the pump bypass valve. Remove the W bypass tubing segment from the pump bypass valve.
5. Stretch outward and lift the R and W tubing collars from the horizontal slots in the tubing support block. Remove the remaining tubing collars from the tubing support block. Disconnect the W bypass segment from the T connector located nearest the white plug at the front of the instrument. The pump segments are now free of the pump.
7. Remove the W and R tubing harness manifolds from the mounting pins.
8. Remove the W line from the reagent pack waste bottle.
9. Remove the R straw from the R bottle in the reagent pack.
10. The old W and R tubing harness is now free from the instrument and can be discarded. The W/R harness part number is PN 07272.
11. Attach the free end of the W bypass tubing segment to the T connector on the front W portion of the harness.

> CAUTION: Do not overstretch the pump segments in the steps that follow. Overstretched pump segments will give inadequate drawing pressure and will require replacement of the segment.

12. Position the W pump segment of the new W/R harness around the lower portion of the pump assembly, stretching the tubing slightly so that the collar closest to the white plug fits into the front retainer slot and the collar closest to the reagent pack straw fits into the rear retainer slot (Figure 5.32).

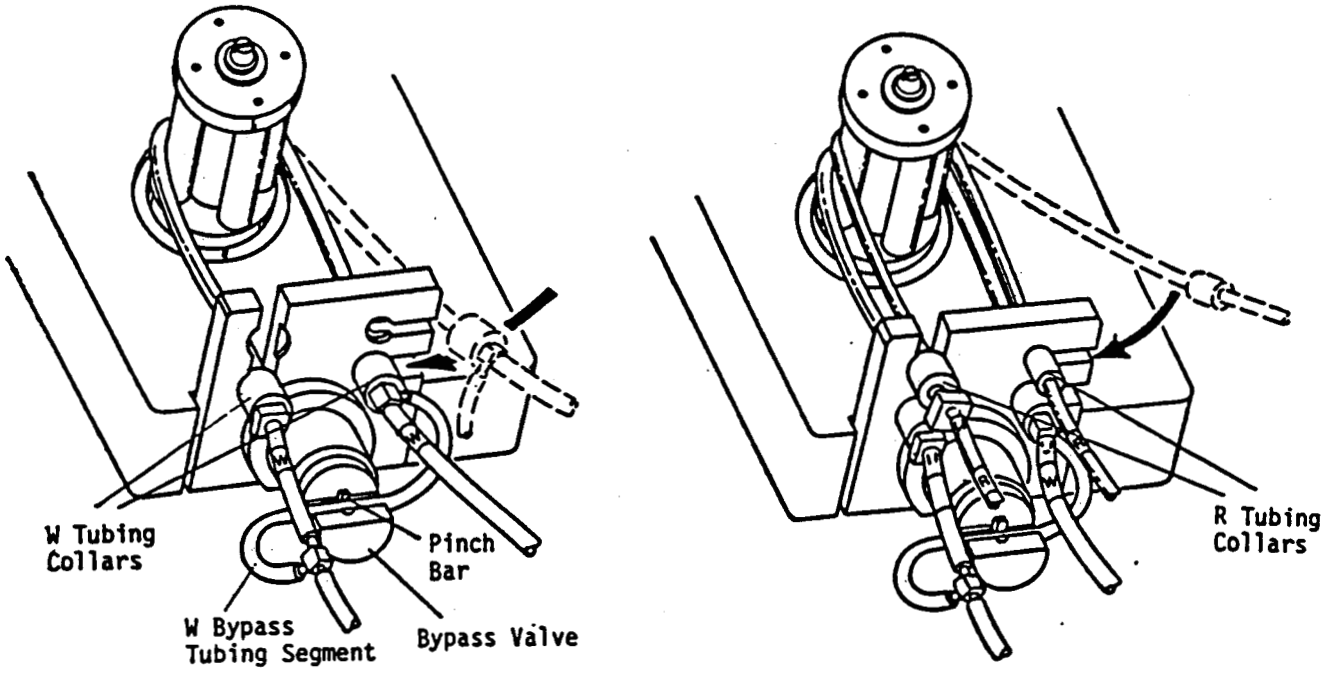


Figure 5.32 Tubing Position Around Pump

13. Insert the W bypass tubing segment into the pump bypass valve by moving the pinch bar out of the way with a small screwdriver or fingernail, and placing the tubing segment in the valve.
14. Position the new R line around the upper portion of the pump assembly, stretching the tubing slightly so that the larger black collar fits into the front retainer slot and the smaller gray collar fits into the rear retainer slot.
15. Press the three small W/R tubing manifold bars onto their pins, making sure that the tubing feeds around smoothly and is not twisted.
16. Insert the W line into the waste container opening and the R straw into the R bottle container opening, making sure the reagent line fittings seat snugly onto the reagent bottles.
17. Thread the other ends of the tubing harness through the appropriate openings into the analyzer compartment and secure the white plugs (Figure 5.33).

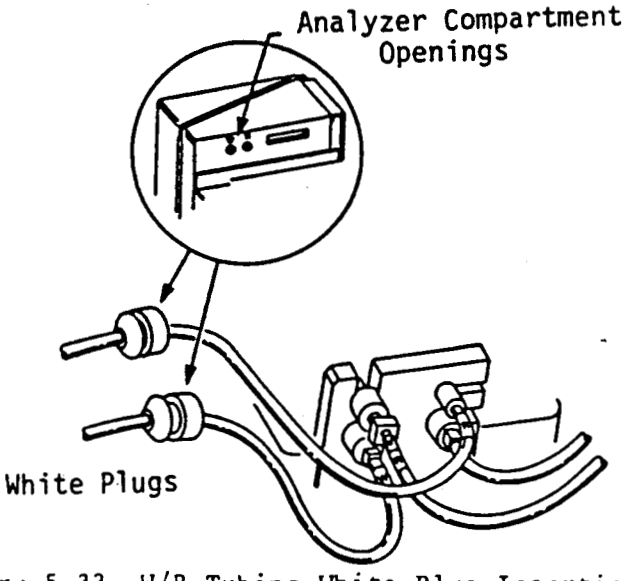


Figure 5.33 W/R Tubing White Plug Insertion

18. Open the analyzer compartment door. Connect the W and R lines to the W and R ports on the reference electrode. Close the analyzer compartment door.
19. Press 5, 4 to draw reference solution into the reference electrode.
20. When the fluid/air transition passes into the reference electrode (about 2 minutes), press 5, 0, 6, 0 to stop aspiration.
21. Press CLEAR, CLEAR, CLEAR, to return to the Ready (Not Ready) for Analysis screen.
22. Close the plexiglass cover.

5.4.13 Reagent Harness Replacement

1. Open the plexiglass cover, exposing the fluids deck.
2. Remove the reagent straws from the F, C, D, A, and B reagent bottles, leaving the W and R lines in place.
3. From the Ready For Analysis screen, press MENU, 2, 7, ENTER to empty the reagent lines.
4. When the cycle is complete, press MENU, 3, 1, 3 to change the PO_2 gain to Low. (Do this to delay automatic flush or calibration cycles for maintenance -- movement of any System Test function will result in delay of the cycles, but the PO_2 gain is the most convenient.)
5. Open the valve pinch bar and pull the tubing out from the valve tubing clips.
6. Remove the 5 tube manifold bar, located in front of the valve, by lifting it off the mounting pins.
7. Locate the manifold connector mounted on top of the reagent preheater (see Figure 5.34). Remove the connector.

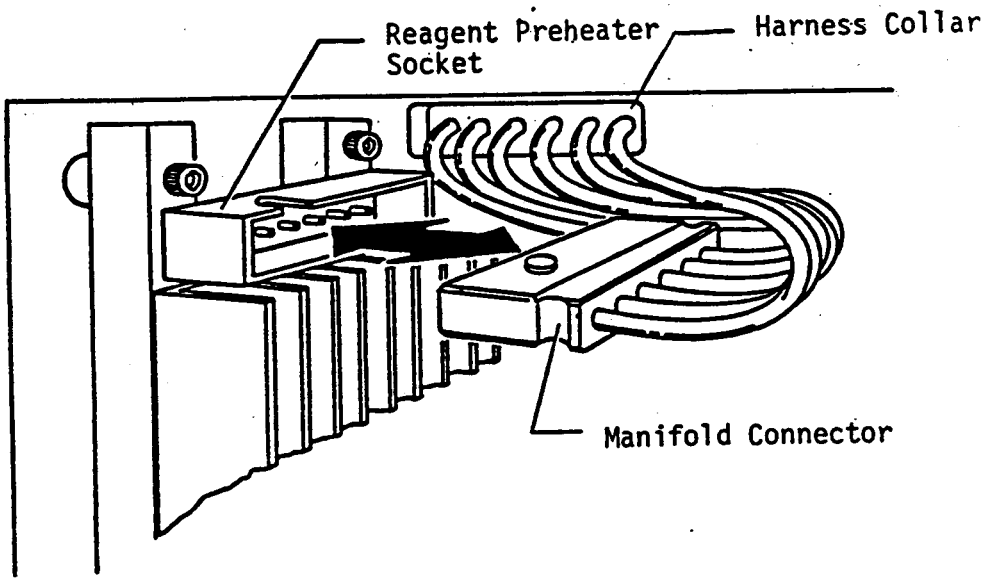


Figure 5.34 Reagent Tubing Harness Manifold Connector

8. Pull the harness collar out of the back of the analyzer compartment and pull the tubing harness out through the slot.
9. Remove the 4 tube manifold bar.
10. Install the new reagent harness (PN 06516) by pressing the 5 tube manifold bar onto the mounting pins located between the pinch valve and the analyzer compartment (Figure 5.35).
11. Position the C, D, A, and B tubings on the pinch valve assembly and close the pinch bar, pulling out on the knob and releasing the knob to lock the bar in place. Ensure that the tubing is correctly positioned on the pinch valve assembly.

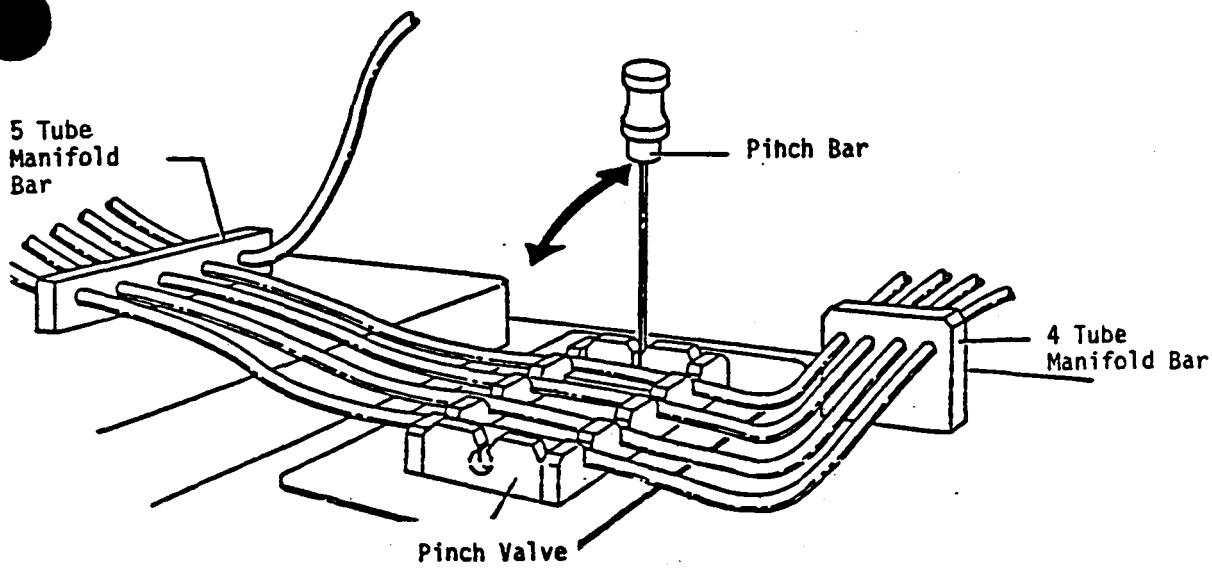


Figure 5.35 Valve Tubing Positioning

12. Press the 4 tube manifold onto the mounting pins located between the reagent pack and the pinch valve.
13. Insert the reagent straws into the appropriate openings in the reagent pack (Figure 5.38).
14. Press down on the reagent line bottle fittings to ensure a snug fit onto the reagent bottles.
15. Feed the connector into the analyzer compartment through the slot in the back of compartment. Firmly seat the harness collar into the analyzer compartment slot.
16. Open the analyzer compartment door and connect the manifold connector into the reagent preheater socket. Close the analyzer compartment door.
17. Press CLEAR, CLEAR, CLEAR, to return to the Ready For Analysis screen.
18. Press Menu, 2, 7, ENTER to initiate a fluid prime cycle, and verify that no fluid leaks are occuring at the manifold connector.
19. Close the plexiglass cover.

5.4.14 Septum Harness Replacement

1. Open the plexiglass cover, exposing the fluids deck.
2. Clamp the C and F lines of the reagent harness.
3. Open the analyzer compartment door.
4. From the Ready For Analysis screen, press MENU, 3, 1, 3 to change the PO_2 gain to Low. (Do this to delay automatic flush or calibration cycles for maintenance -- movement of any System Test function will result in delay of the cycles, but the PO_2 gain is the most convenient.)
5. Locate the manifold connector at the bottom of the Reagent Preheater. Remove the connector from the Reagent Preheater (Figure 5.36).

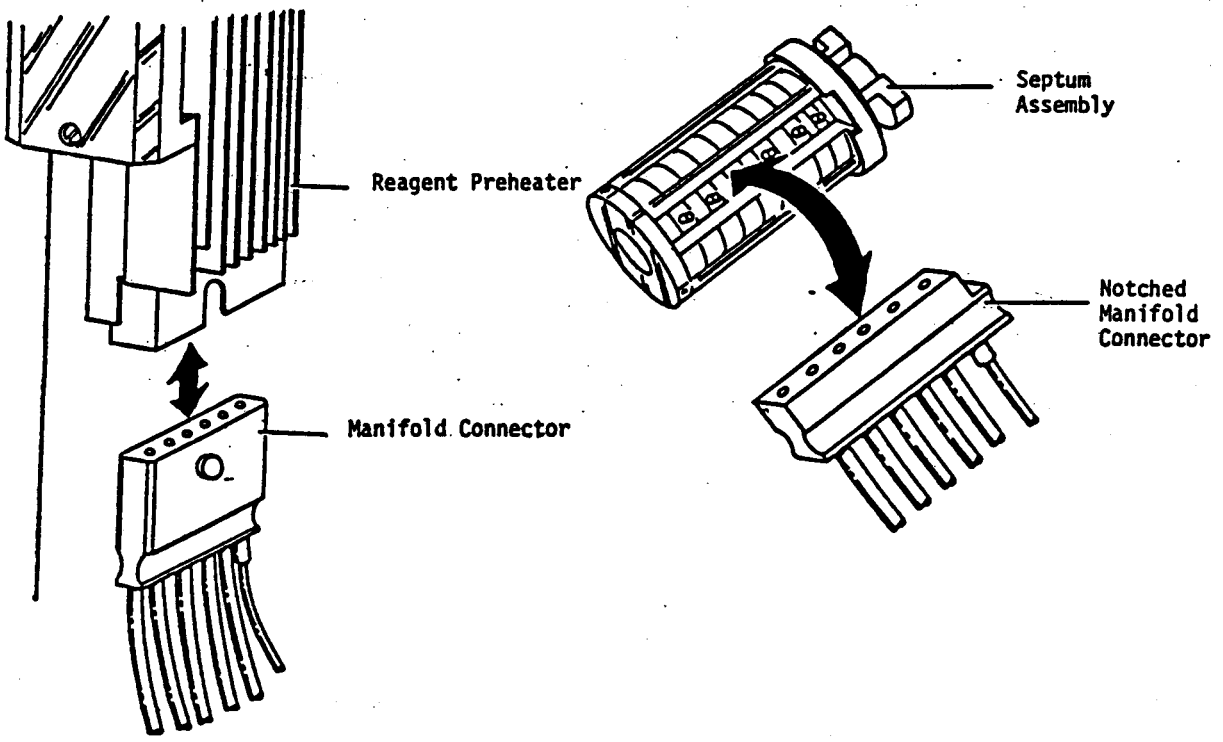


Figure 5.36 Septum Harness Installation

6. Locate the manifold connector on the septum assembly. Remove the manifold connector from the assembly, freeing the old Septum Harness. Discard the old Harness.
7. The septum harness part number is PN 06517. Plug the notched manifold connector of the new harness into the septum assembly fitting.
8. Loop the septum harness below the sampler assembly and connect the other end to the reagent preheater. The manifold connector is keyed with a projection to allow only the correct fit into the reagent preheater.

NOTE: The septum harness manifold connectors do not fit tightly into their sockets.

9. Close the analyzer compartment door.
10. Unclamp the C and F lines of the reagent harness.
11. Close the plexiglass cover.
12. Press CLEAR, CLEAR, CLEAR, to return to the Ready For Analysis screen.
13. Press 2, 7, ENTER to initiate a fluid prime cycle, and verify that no fluid leaks are occuring at the manifold connectors.

5.4.15 Reagent Pack Replacement

In addition to system-initiated prompting for changing the reagent pack, the reagents level can be checked visually through the window slot on the reagent pack. Change the reagent pack as follows:

1. Open the plexiglass cover.
2. Remove the F, C, D, A, B, and R reagent straws from the reagent pack. Wipe the outside of each straw with a paper towel as it is pulled from the pack. Leave the W tubing in place.
3. From the Ready For Analysis screen, press MENU, 2, 7, ENTER, performing a fluid prime cycle with air to empty the reagent lines.
4. If the reagent pack is being replaced as a routine procedure continue with Step 9. If the Reagent Pack is being replaced as part of a troubleshooting procedure, continue with Step 5.
5. When the prime cycle is complete, insert the straws into a beaker of deionized water (see Figure 5.37).

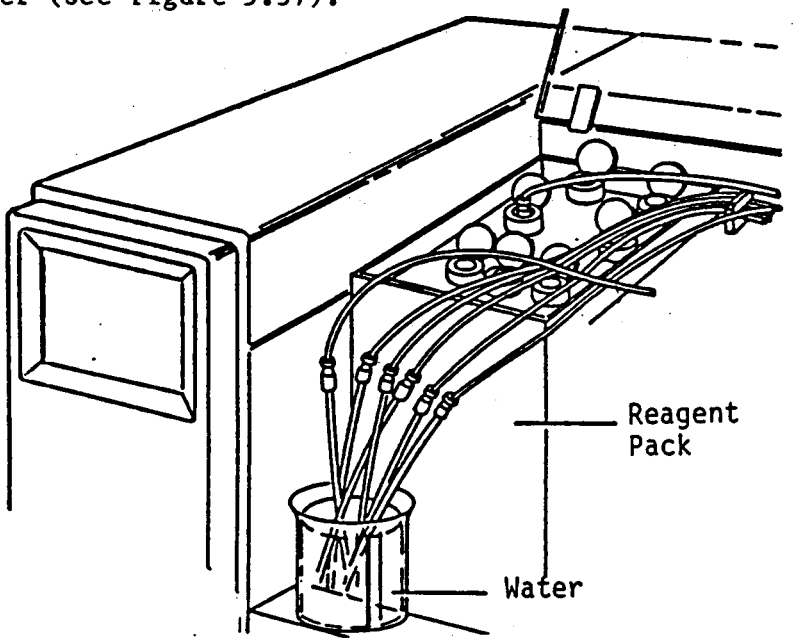


Figure 5.37 Distilled Water Reagent Harness Cleaning

6. Press MENU, 2, 7, ENTER to initiate a fluid prime cycle.
7. When the prime cycle is complete, remove the F, C, D, A, B, and R straws from the beaker, and wipe the outside of the straws dry with a paper towel.
8. Press MENU, 2, 7, ENTER to initiate a prime cycle to flush the deionized water from the tubing.
9. When the prime cycle is completed, lift out the W tubing, then remove and discard the used reagent pack.
10. Shake the new reagent pack (PN 05415), remove the cellophane wrapping, and position the pack in the reagent pack bay so that the reagent level viewing slot is facing forwards.
11. Flip open the caps on the reagent bottles.

12. Insert the color-coded straws into the appropriate colored bottle caps on the top of the reagent pack (see Figure 5.38) and press the fittings down snugly onto reagent bottles. The colored letter patches on the straw tubing corresponds to the respective color patches by the bottle caps on the reagent pack.

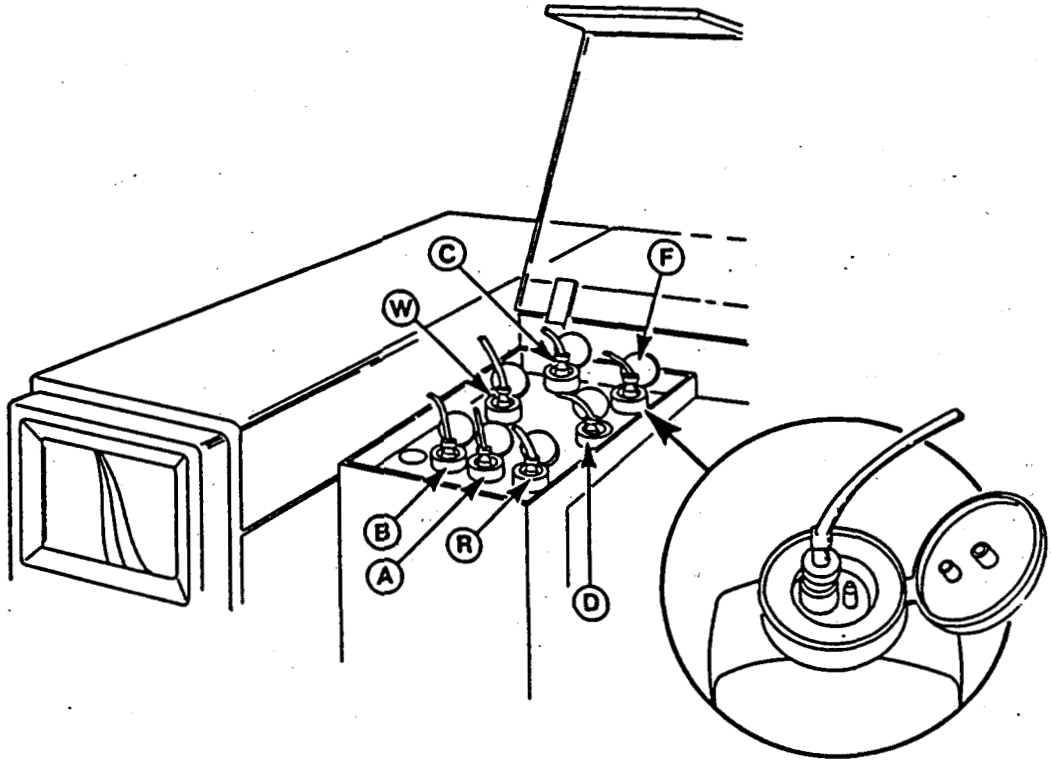


Figure 5.38 Reagent Pack Tubing Positions

NOTE: If a straw is accidently inserted in the wrong reagent bottle, e.g. the A tubing is pushed through the R opening, the tubing harness must be flushed with deionized water as follows:

a. Insert the W tubing into the W bottle in the new reagent pack.
b. Wipe the contaminated straw with a paper towel.
c. Insert the straws into a beaker of deionized water.
d. Repeat Steps 6 - 8, 11, and 12.

13. Press MENU, 2, 9, and enter the expected number of analyses. Press ENTER to initialize the Analyses Remaining Counter to this value.
14. Replace the septum assembly per Section 5.4.16.
15. Press 2, 7, ENTER to prime the reagent lines.
16. After the prime cycle is complete, press CLEAR, CLEAR, CLEAR to return to the Ready For Analysis screen.
17. Press CAL, ENTER to calibrate the instument.

5.4.16 Septum Assembly Replacement

The septum assembly should be replaced with each reagent pack. Failure to replace the septum assembly will result in worn, leaking septa with intermixing of reagents.

1. From the Ready For Analysis screen, press MENU, 3, 1 to access the System Test screen.
2. Press 3 to change the PO_2 gain to Low. (Do this to delay automatic flush or calibration cycles for maintenance -- movement of any System Test function will result in delay of the cycles, but the PO_2 gain is the most convenient.)
3. Open the analyzer compartment door.
4. Clamp off the C and F tubings directly above the septum assembly.
5. Disconnect the septum harness manifold connector from the septum assembly.
6. Remove the septum assembly by giving the assembly a 1/4 turn clockwise and pulling out.
7. Plug the manifold connector into the new septum assembly.
8. Install the septum assembly (Figure 5.39), sliding the assembly over the end of the probe so that the rectangular piece on the end fits into the septum assembly opening in the baseplate of the sampler assembly. The septum harness manifold connector should be to the left.

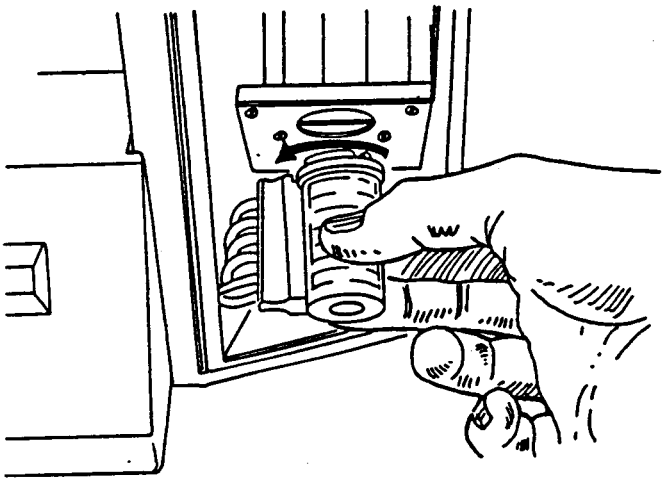


Figure 5.39 Installing The Septum Assembly

Turn the assembly 1/4 turn counterclockwise until snug. The septum harness manifold plug should be at the lower right of the assembly; if it is not, remove the septum assembly from the septum assembly opening, rotate the assembly 1/2 turn, and reinsert.

9. Remove the clamps from the C and F lines.
10. Close the analyzer compartment door.
11. Press CLEAR, CLEAR, CLEAR, to return to the Ready For Analysis screen.

5.4.17 Sampler Probe-S Line Replacement

1. From the Ready For Analysis screen, press MENU, 3, 1, 6, 8, 5, 4, to aspirate air to purge the fluid out of the flow path.
2. After 10 seconds, press 5, 0, 6, 0 to stop aspiration.
3. Press 3 to change the PO_2 gain to Low. (Do this to delay automatic flush or calibration cycles for maintenance -- movement of any System Test function will result in delay of the cycles, but the PO_2 gain is the most convenient.)
4. Open the analyzer compartment door.
5. Disconnect the probe-S line from the sample preheater by pulling the crimp lock off the sample preheater connector, then pulling the S line off the sample preheater (Figure 5.40).

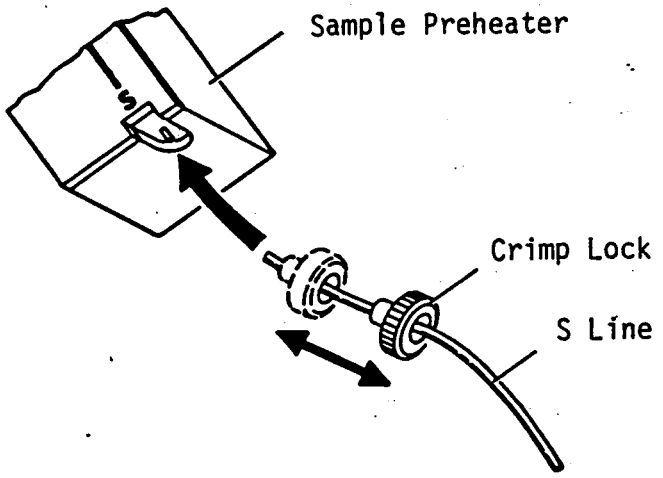


Figure 5.40 Probe-S Line Removal from Sample Preheater

6. Remove the septum assembly with the septum harness attached, by turning the assembly a 1/4 turn clockwise.
7. Press 6, 8 to move the probe to position 8.
8. Loosen the thumbscrew located at the top of the probe, then, grasping the probe mounting block, remove the probe-S line unit (Figure 5.41).

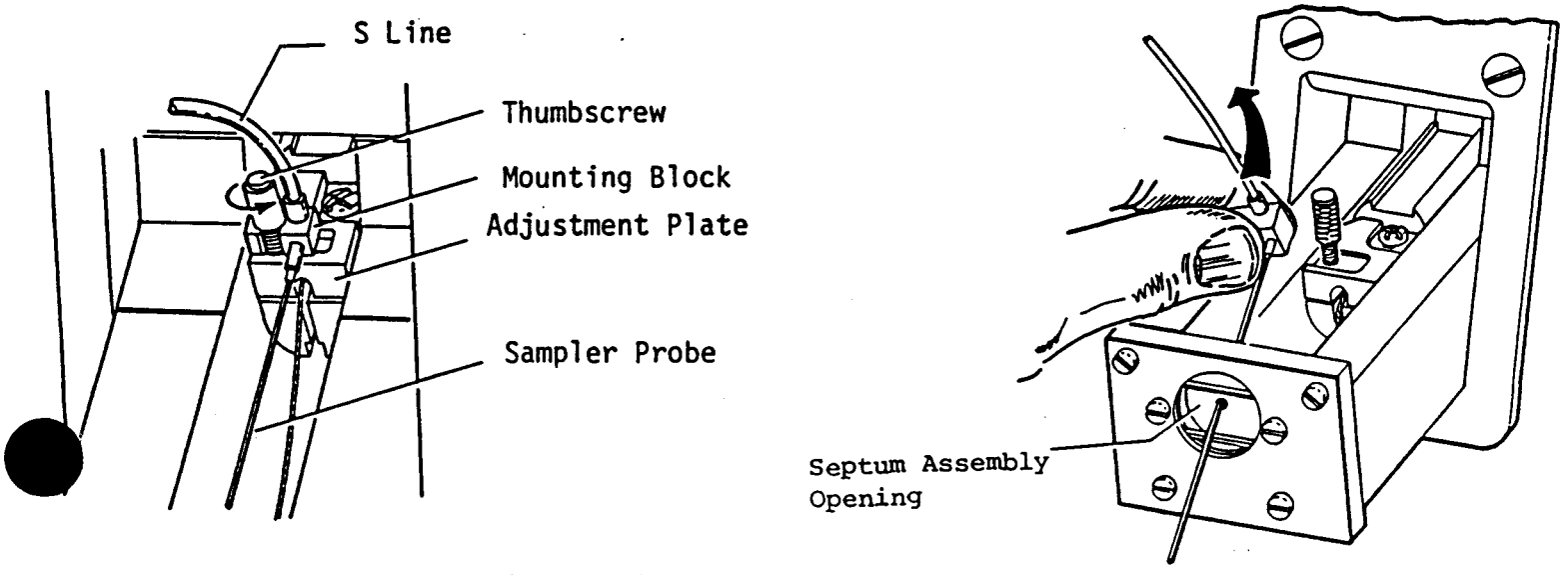


Figure 5.41 Sampler Probe Removal

9. Replace the probe-S line (PN 06523) by first sliding the probe tip through the septum assembly opening all the way to the mounting block. Then move the block back and around the thumbscrew to hook it around the thumbscrew. Finally, tighten the thumbscrew to affix the sampler mounting block to the adjustment plate.
10. Replace the septum assembly (with attached Septum Harness) by sliding the assembly over the end of the probe so that the rectangular piece on the end fits into the septum assembly opening in the baseplate of the sampler assembly. The septum harness manifold connector should be to the left. Turn the assembly 1/4 turn counterclockwise until snug. The septum harness manifold connector should now be at the lower right of the assembly; if it is not, remove the septum assembly from the septum assembly opening, rotate the assembly 1/2 turn, and reinsert.
11. Perform a probe placement test as follows:

    a. Press 6, 9 to move the probe to position 9.
    b. Slide the probe adjustment tool (PN 07190) over the probe and hold it firmly to the base of the sampler assembly so that the probe tip extends toward the stepped end. The probe tip should be in between the high and low steps. If it is not, adjust as follows:

        - Using a phillips head screwdriver, loosen the screw that holds the sampler adjustment plate to the instrument.
        - Advance the plate (with the probe) up or down as needed.
        - Tighten the screw holding the probe secure.
        - Verify that the probe tip is positioned between the 2 steps.
        - If necessary, repeat the procedure.

12. Connect the probe-S line to the connector on the bottom of the sample preheater and secure the connection by sliding the crimp lock over the connection.
13. Press 6, 1, 5, 4 to aspirate flush solution to check for leaks around the S line connection. After checking, press 5, 0 to turn the pump off. If a leak occurs, reseat the S line on the connector.
14. Press 6, 0, CLEAR, CLEAR, CLEAR, to return to the Ready For Analysis screen.
15. Close the analyzer compartment door.

5.4.18 Flow Path Component Replacement

Replace the preheater and/or flow cell by performing steps 1 - 9, then proceeding to the appropriate component. Refer to Figure 5.42 throughout this procedure.

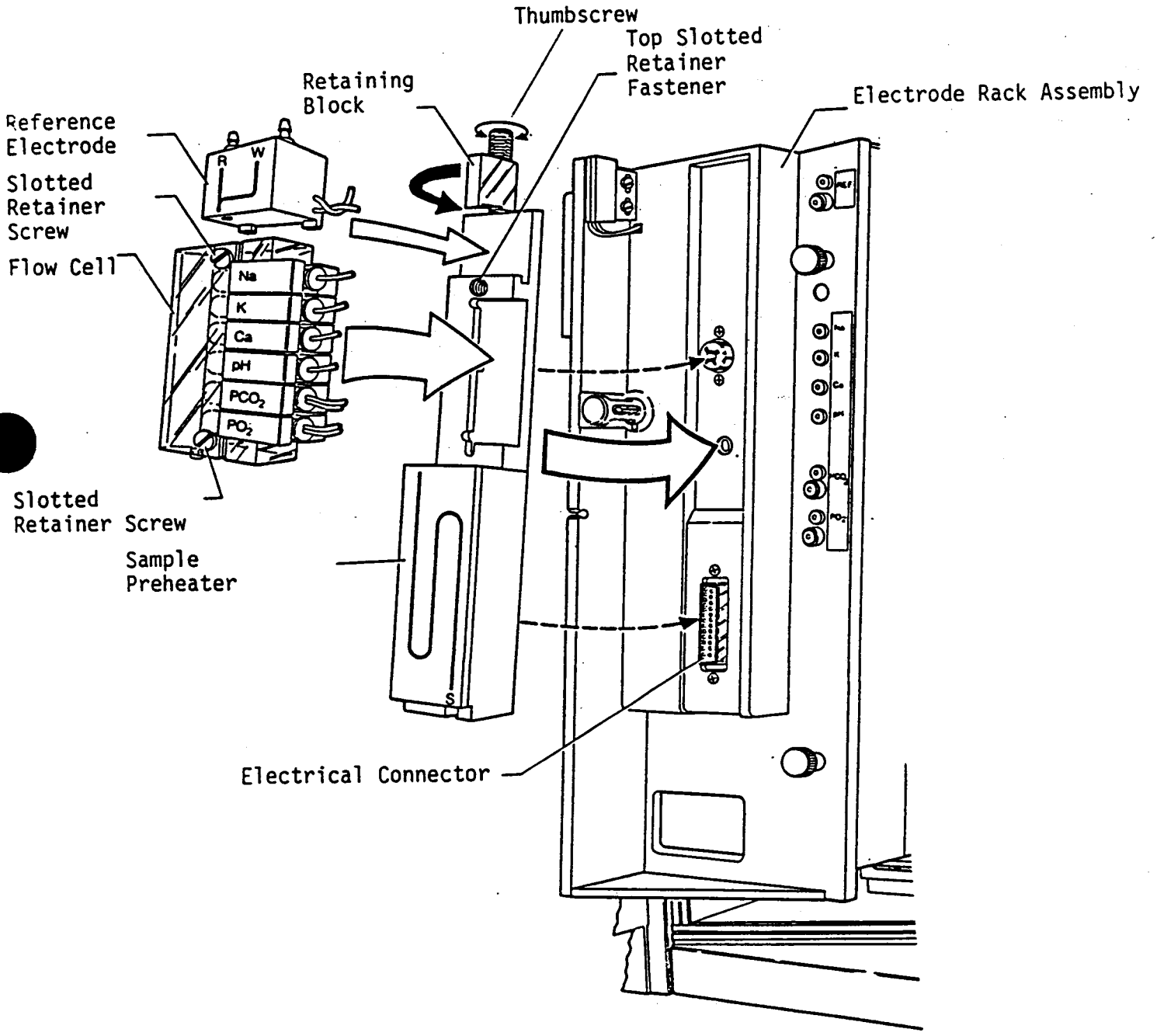


Figure 5.42 Flow Path Component Replacement

1. From the Ready For Analysis screen, press MENU, 3, 1, 6, 8, 5, 4 to empty the flow path.
2. After 10 seconds, press 5, 0, 6, 0 to stop aspiration and retract the probe.
3. Press 3 to change the PO_2 gain to Low. (Do this to delay automatic flush or calibration cycles for maintenance -- movement of any System Test function will result in delay of the cycles, but the PO_2 gain is the most convenient.)
4. Open the analyzer compartment door.
5. Clamp and disconnect the W and R lines from the reference electrode.
6. Unplug all electrode cables from the electrode rack assembly.
7. Disconnect the S line from the sampler preheater by sliding the crimp lock off the connector and pulling the S line off.
8. Remove the preheater-flow cell-reference electrode assembly by first turning the bottom slotted retainer screw 1/4 turn counterclockwise then pulling the assembly straight off the guide pin and electrical connectors.
9. Loosen the thumbscrew located on top of the reference electrode, turn the retaining block to the side, and retighten the thumbscrew.
10. Lift the reference electrode up and out of the way of the flow cell.
11. Replace the appropriate component as follows:

Flow Cell Replacement

a. Turn the top slotted thumbscrew 1/4 turn counterclockwise and lift the flow cell (with the electrodes still inserted) off the sample preheater.
b. If the flow cell (PN 06017) is being replaced, remove the sodium electrode and insert it into the new flow cell. Repeat this procedure for the other electrodes and washers, avoiding any mixup by replacing each washer and electrode immediately upon removal.
c. Check the new flow cell for intact interconnect tubings.

Sample Preheater Replacement

a. Remove the flow cell (with the electrodes still inserted) by turning the top slotted thumbscrew 1/4 turn counterclockwise and lifting it off the sample preheater.
b. Reassemble the flow cell to the new sample preheater (PN 06525) as follows.

Reassembly Procedure

12. Reattach the flow cell to the sample preheater back plate as follows (refer to Figure 5.42).

a. Set the flow cell into the recess on the sample preheater aligning the right surface of the flow cell flush with the right side of the back plate. Ensure that the flow cell interconnect tubing is seated properly on the sample preheater top connector.
b. Turn the top slotted retainer screw 1/4 turn clockwise.

13. Replace the reference electrode on top of the flow cell by placing the electrode on top of the flow cell, aligning the electrode sides with the backplate sides. Ensure that the reference electrode connector is seated properly on the flow cell interconnect tubing.
14. Loosen the retaining block thumbscrew, center the retaining block in the depression on top of the electrode, and retighten the thumbscrew.
15. Replace the preheater-flow cell-reference electrode assembly by aligning the guide pin and pressing the assembly onto the electrical connectors, then turning the bottom slotted retainer screw 1/4 turn clockwise to engage the electrode rack assembly.
16. Plug all cables into the electrode rack assembly.
17. Reattach the S line to the sample preheater.
18. Attach and unclamp the W and R lines to the reference electrode.
19. Verify that the flow path is unobstructed as follows:

    a. Press 6, 1, 5, 4 to aspirate flush solution.
    b. Observe the waste line for proper flow for 5 seconds, then stop aspiration by pressing 5, 0. If the flow is obstructed, check the interconnections between the S line - preheater, preheater - flow cell, and flow cell - reference electrode, and check that the W and R tubings are properly connected.

20. Close the analyzer compartment door.
21. Perform a conditioning cycle with whole blood as follows:

    NOTE: All electrodes must be in the flow cell during a Flow Cell Conditioning cycle.

    a. Fill a 2 ml sample cup 1/2 full of whole blood.
    b. From the Ready For Analysis screen, press MENU, 2, 5 and present the blood to the probe.
    c. Press ANALYZE to aspirate the blood. Withdraw the cup when the probe retracts.

22. Verify good flow (no bubbles) of solution as follows:

    a. Press 6, 1, 5, 4 to aspirate flush solution.
    b. Observe the waste line for proper flow for 5 seconds. Stop aspiration by pressing 5, 0. If bubbles are seen, flush the flow cell and verify correct positioning of the washers in the flow cell. Repeat aspiration, pressing 5, 4 then 5, 0. If bubbles are still seen, check the interconnections between the S line - preheater, preheater - flow cell, and flow cell - reference electrode, and check that the W and R tubings are properly connected.

22. Press 3, 6, 0, CLEAR, CLEAR, CLEAR to return to the Ready For Analysis screen. If the instrument displays the Not Ready screen with the AIR BATH NOT READY status message, wait until the instrument reaches operating temperature and the Ready For Analysis screen is displayed.
23. Press CAL, ENTER to perform a two-point calibration.

5.4.19 Barometric Pressure Module Replacement

1. From the Ready For Analysis screen, press MENU, 3, 1, 6, 8, 5, 4 to aspirate air to purge fluids out of the flow path.
2. After 5 seconds, press 5, 0, 6, 0 to stop aspiration and return the probe to the home position.
3. Open the analyzer compartment door.
4. Disconnect the S line from the sample preheater.
5. Clamp and disconnect the W and R lines from the reference electrode.
6. Remove the electrode rack assembly by loosening the 2 thumbscrews located to the right of the sample preheater (Figure 5.43). Pull the Assembly off the electrical connectors. Locate the barometric pressure module (black box) on the upper left side of the electrode rack assembly.

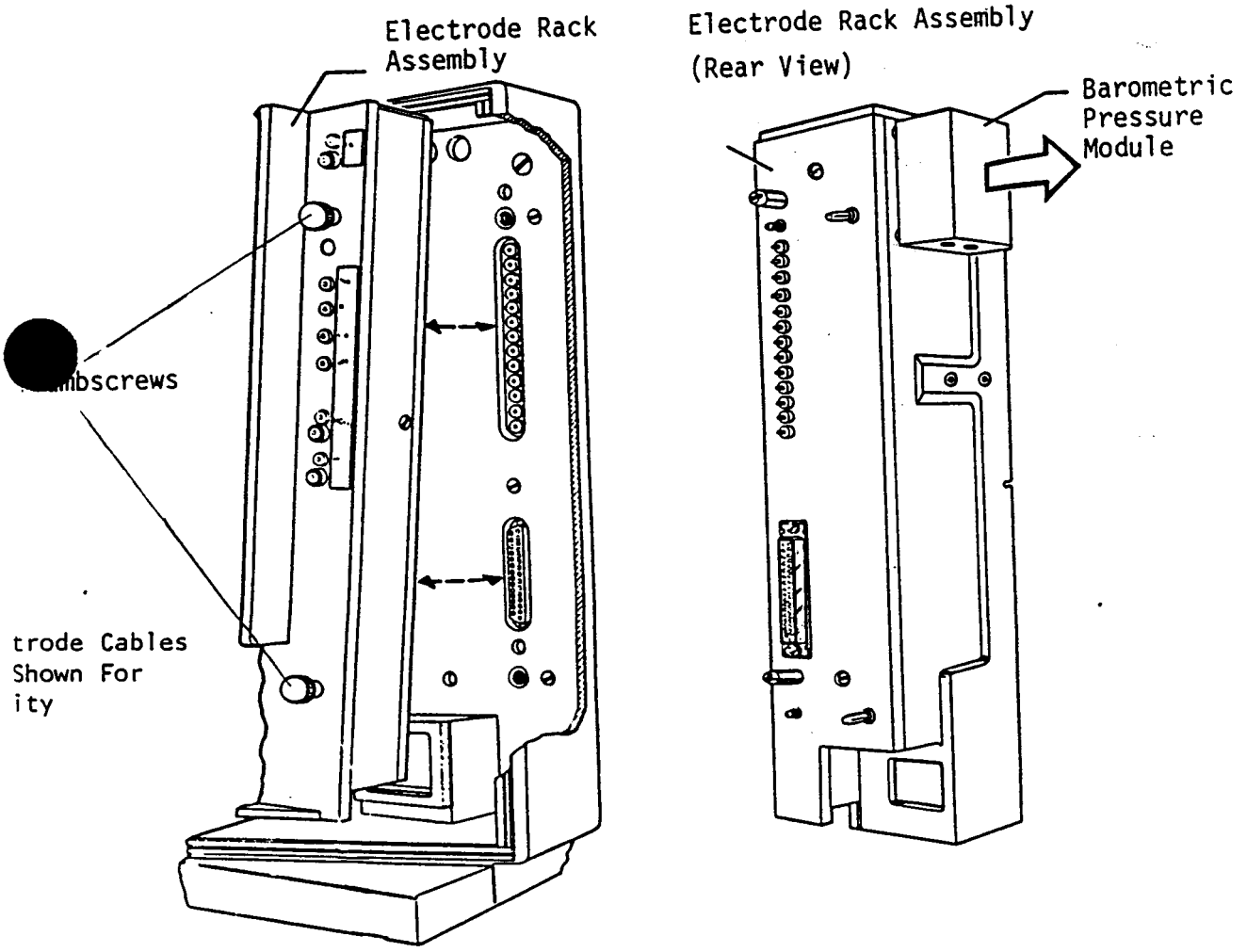


Figure 5.43 Barometric Pressure Module Replacement

7. Remove the barometric pressure module from the electrode rack assembly by pulling the Module off the assembly.
8. Attach the new barometric pressure module to the electrode rack assembly, making sure that the end of the Module with the holes is facing downward.
9. Reattach the electrode rack assembly to the instrument.
10. Reconnect the S line to the sample preheater connection, seating it firmly on the connector before sliding the crimp lock over the connection.
11. Reconnect the W and R lines to the reference electrode and unclamp the tubing.
12. Close the analyzer compartment door.
13. Press CLEAR, CLEAR, CLEAR. The CHECK BAROMETER PRESSURE status message will appear on the Not Ready screen, indicating that the instrument barometer is not initialized. Initialize the barometer as follows:

    a. Press MENU, 4, 0 (or your password), 8 then either:

    - Press 4 to select automatic barometric tracking, or
    - Do not press a key, thereby selecting manual entry of external barometric pressures (see Section 2.2.8).

    b. Press CLEAR, CLEAR to return to the Main Menu.

14. Perform a barometer check as follows:

    a. Press MENU, 1, 3, accessing the Set Barometric Pressure screen.
    b. Note the barometric pressure reading. The barometric pressure reading should agree within ± 2 mm mercury with a reliable reference value such as a lab barometer or an altitude-corrected weather bureau reading. If the values are not in agreement, see Section 3.2.3 to calibrate the barometer.

15. Press CLEAR, CLEAR, CLEAR to return to the Ready For Analysis screen.

4.20 Printer Paper Replacement

When the red line appears on the edge of the paper the paper supply is low and should be replaced as follows:

1. Pull out printer assembly located under the reagent pack bay (Figure 5.44).

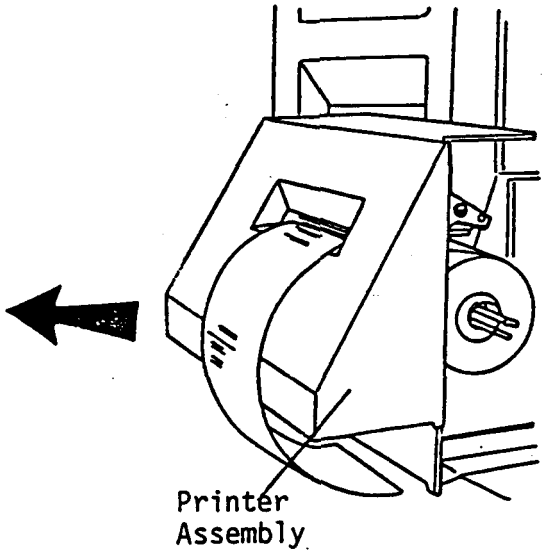


Figure 5.44 Printer Assembly Access

2. Lift up the black print head loading arm to release the paper (Figure 5.45). Make sure the loading arm is lifted to fullest extent.

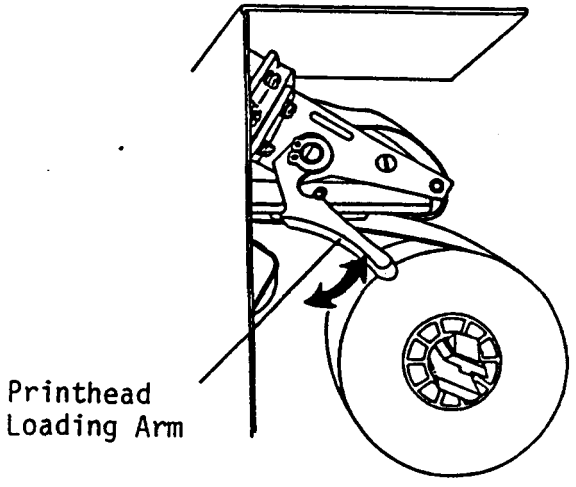


Figure 5.45 Paper Release

3. Pull the empty paper roll off and discard.
4. With paper feeding from top of roll, slide new roll (PN 00026) onto shaft until it is flush with the plate and the large portions of the shaft snap out.
5. Feed the paper end between the printhead and rubber roller.
6. Grasp the end of the paper and pull until 2-3 inches extend out of slot.
7. Push the black print head loading arm down.
8. Push the printer assembly back into the instrument.
9. From the Ready For Analysis screen, press MENU, 3, 7, 6 to obtain a character printout to verify proper operation.
10. Press CLEAR, CLEAR, CLEAR to return to the Ready For Analysis screen.

5.4.21 Printhead Cleaning

Printer printhead cleaning is required when the print density is uneven due to residue buildup. Generally, the most often printed characters or dots are most prone to residue buildup with resulting light and irregular image. To clean the printhead:

1. Pull out the printer assembly located under the reagent pack bay.
2. Lift up the printhead loading arm to release the paper. Make sure the loading arm is lifted to fullest extension.
3. Pull the paper out from under the printhead.
4. Moisten a cotton swab with alcohol and gently clean the printhead (Figure 5.46).

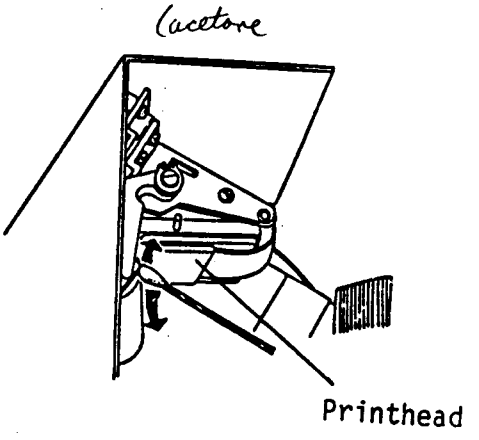


Figure 5.46 Printhead Cleaning

5. Repeat several times and allow the alcohol to evaporate completely.
6. Feed the paper back through the printhead.
7. Push the printhead loading arm completely down.

5.4.22 Fan Filter Replacement

The fan filter, located on the fan at the lower left side of the instrument, is held in place by the snap-on grating. When dirty, or on a monthly basis, vacuum the fan filter. Replace the filter every 6 months.

1. Insert a screw driver into the grating and free the filter by gently prying the grating out from the fan housing (Figure 5.47).
2. Vacuum or discard the filter.
3. Hold the new filter (PN 07158, 10/bag) onto the inner side of the grating, and press the grating back into the fan housing until it snaps into place.

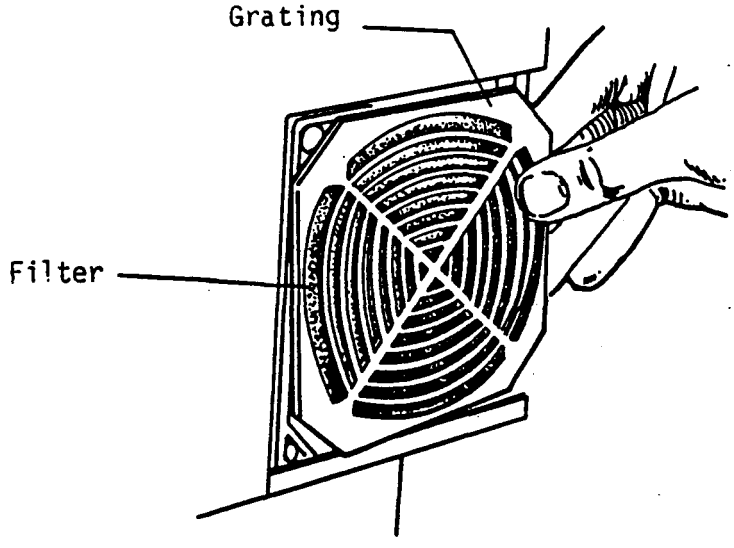


Figure 5.47 Fan Filter Replacement

5.4.23 Gas Cylinders Replacement, Regulator Adjustment, and Hose Fitting

To check gas amount and pressure, refer to the following Gas Regulator Adjustment section.

Gas Cylinder Replacement

1. Turn the gas cylinders off at the regulators.
2. Remove the regulators from the cylinders, and remove the empty cylinders from the stands.
3. Place the new cylinders (Cal. Gas A - PN 06586, Cal. Gas B - PN 06587) in the stands (PN 06546/stand).

   NOTE: When attaching the gas regulators, ensure proper alignment by aligning the T tightener with the small indentation.

4. Attach the regulators to the new cylinders.
5. Turn the gas regulator on with the gas wrench (PN 06547). Verify that the gas delivery is at 5 ± 1 PSI. If gas delivery is not in this range, adjust the regulators per the Gas Regulator Adjustment procedure.
6. Check all junctions on the cylinder valve fittings for leaks with leak detecting agent. If leaks are detected, check the washer at the valve-cylinder junction for proper seal, reposition the regulator on the tank, and tighten the fitting.
7. From the Ready For Analysis screen, press MENU, 2, 6, ENTER to perform a gas prime.
8. Verify that both humidifier wells are bubbling.

   NOTE: If the gas calibration values of new gas cylinders are different than the previous cylinders, set new gas cal values (see Section 5.1.8).

9. Press MENU, 2, 1, ENTER to calibrate the gas electrodes.

Gas Regulator Adjustment

With both gas cylinder regulators (PN 06545/regulator) completely open, verify that the gas delivery pressure is at approximately 5 PSI ± 1 and that the volume is at about 2000 PSI. If the gas pressure is incorrect, adjust the regulator as follows:

1. Remove the cover nut from the front of the regulator with a 1/2-inch wrench.
2. Insert a 1/8-inch allen wrench into the socket and turn (clockwise for increasing PSI) to set the gas delivery pressure at 5 ± 1 PSI.
3. Replace the cover nut.

Gas Hose Connection

1. Place the gas tanks approximately 5 feet or less from the gas input ports.
2. Attach the gas regulators to the tanks and secure the tanks with stands.

   NOTE: When attaching the gas regulators, ensure proper alignment by aligning the T tightener with the small indentation.

3. Slide the spring hose clamps over each end of the 2 neoprene hoses (PN 06548).
4. Slide an end of a hose over the fitting on the gas tank regulator and secure the hose with the spring hose clamp (PN 06549). Repeat for the other hose and regulator.
5. Remove the right instrument side cover by unscrewing the 3 phillips head screws then lifting off.
6. Attach the neoprene hoses to the two gas ports on the right side of the instrument making sure to attach hose A to fitting A and hose B to fitting B (Figure 5.48). Secure each hose-connector junction with a spring hose clamp.

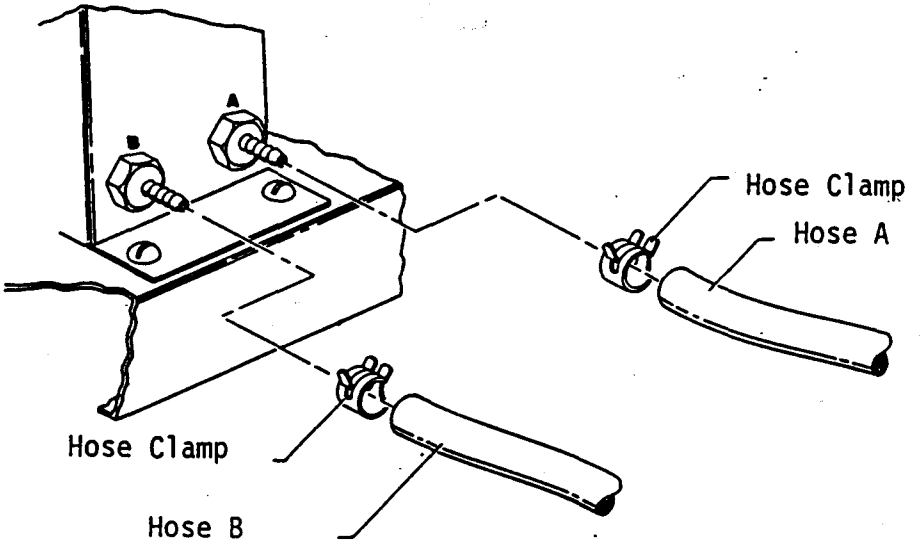


Figure 5.48 Gas Port - Hose Attachment

5.4.24 Fuse Replacement

If the Analysis Ready Light is off and the instrument does not respond, check the external fuse as follows:

1. Unplug the instrument from the AC line voltage.
2. Access the external fuse, located at the rear of the instrument next to the socket for the line cord (Figure 5.49), by turning the plastic slotted fuse cover 1/2 turn.

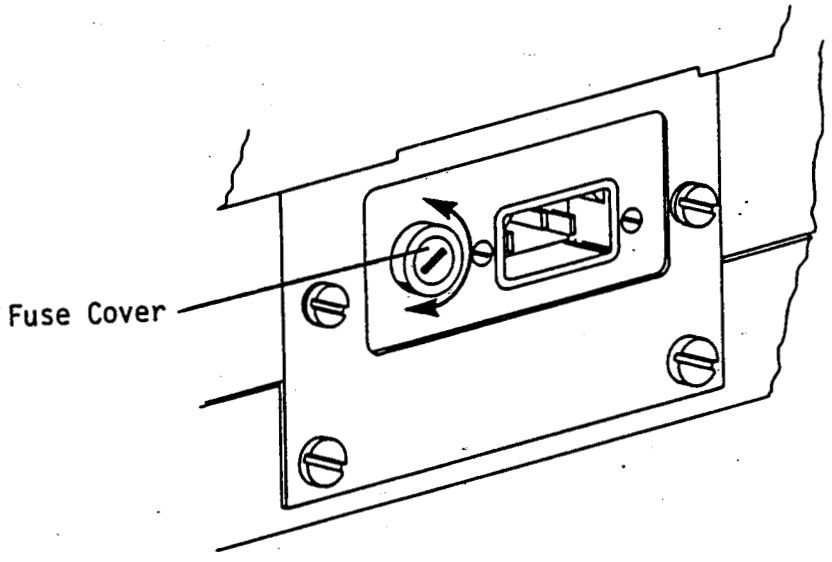


Figure 5.49 External Fuse Access

3. Remove the fuse and check to see if "blown". If fuse is "blown" note the line voltage indicated on the serial number plate located next to the line cord, and replace with the fuse indicated in Table 5.2. If the fuse is intact, contact NOVA Technical Service for assistance.

Table 5.2 Fuses

Line Voltage	Fuse
100	5A SLO-BLO
120	4A SLO-BLO
200	2.5A SLO-BLO
220	2A SLO-BLO
240	2A SLO-BLO

4. Plug the instrument back into the AC line voltage.

5.4.25 Shutdown Procedure

1. Clean the flow path with cleaning solution (PN 06979) per section 5.4.1.
2. Perform a deionized water purge per steps 1 - 7 of section 5.4.14.
3. Cap the reagent pack bottles.
4. Unclip the PCO_2 and PO_2 electrodes from the Flow cell. Remove the acrylic cap from the PCO_2 or the membrane from the PO_2 electrode and drain the Electrolyte solution from the electrode. Rinse the parts of the electrodes that were in contact with the Electrolyte solution with deionized water , replace the PCO_2 acrylic cap and put membranes onto the electrodes for protection (Sections 5.4.8 & 5.4.9, omitting replacement of the Electrolyte solution. Replace the electrodes in the flow cell.
5. Draw the water out of the gas humidifiers with a syringe.
6. Turn off the gases at the regulators.
7. Unplug the instrument.

5.5 Recommended Spare Parts and Supplies

It is advisable to keep a small quantity of spare parts and supplies to provide uninterrupted operation of the Stat Profile 1. The following list contains the catalog number and recommended quantity for each spare item.

DESCRIPTION	QUANTITY	ITEM #
Calibration Gas A	1	06586
Calibration Gas B	1	06587
Regulator	1	06545
Flow Cell	1	06017
Calcium Electrode	3	06007
PCO_2 Electrode	1	07541
pH Electrode	1	06013
PO_2 Electrode	1	06015
Potassium Electrode	1	06009
Reference Electrode	1	06025
Sodium Electrode	1	06011
PCO_2 Membrane Kit	2	07543
PO_2 Membrane Kit	2	06569
Washer Replacement Kit	2	07159
Reagent Harness	1	06516
Septum Harness	1	06517
W/R Harness	1	07272
W/R Tubing Segments	1	07501
Interconnect Tubing	1	07161
Reagent Pack	2	05415
Electrode Cleaning Solution	1	06979
External Control 1, Acidosis	2	06550
External Control 2, Normal	2	06551
External Control 3, Alkalosis	2	06552
Hematocrit Level 1, Low Normal	2	06555
Hematocrit Level 2, High Normal	2	06556
PCO_2 Electrolyte Solution	1	06553
PO_2 Electrolyte Solution	1	06554
pH/PCO_2 Cond'ing Solution	2	06857
Na Conditioning Solution	2	06856
Sample Preheater (Flow Cell holder)	1	06525
Capillary Adapters	1	06529
Printer Paper	2	00026
Filters (10/bag)	1	07158
Sampler Probe-S Line Kit	2	06523

Reference electrode

Na^+, K^+, pH, Ca^{++} ← problem cell ∞ or a combo

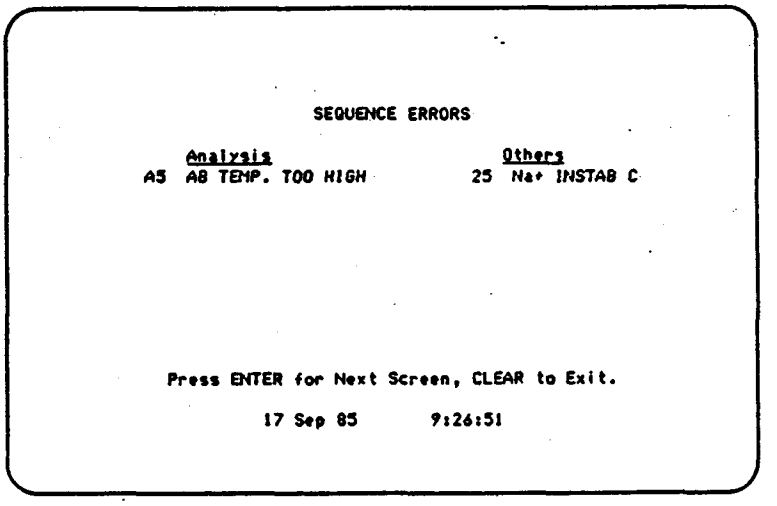
6 TROUBLESHOOTING

This section begins with the error codes and the Status screens where these codes are found. Next, the procedures to solve the error codes are given. Finally, the Service Menu, the menu accessed for troubleshooting, is explained.

6.1 Error Codes

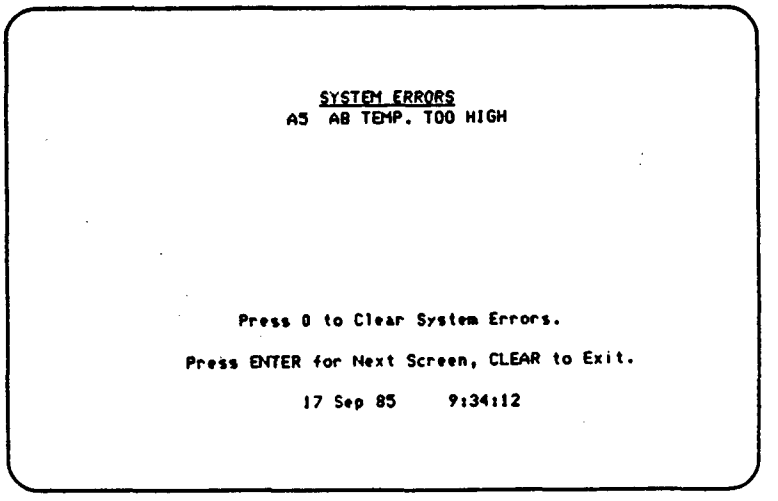
The system program monitors and self-diagnoses the instrument for errors. If an error occurs during use, the error code and the message CHECK STATUS will be displayed. There are two relevant status screens for determining error codes; the Sequence Error Screen, and the System Error Screen, explained as follows. From the READY (NOT READY) FOR ANALYSIS Screen, press STATUS twice to display the SEQUENCE ERROR Status Screen.

SEQUENCE ERROR Status Screen



The Sequence Error Screen displays errors which occur during an analysis or calibration cycle and are mainly electrode or fluidic in nature. Press STATUS a third time to display the SYSTEM ERROR Status Screen.

SYSTEM ERROR Status Screen



The System Error Screen displays errors which occur when a hardware or software problem is detected within the instrument.

All of the reported Error Codes are broken down into two catagories, Minor and Major error codes. During an analysis when the system detects a Minor error the CRT will display a flashing result and the printed result will contain a question mark (?) next to it. Any flashing result or printed result with a question mark should be interpreted with extreme caution. If a Major error is detected, values will not be displayed or printed for the incorrect channel. The possible error codes available are listed in Table 6.1.

Table 6.1 STAT PROFILE 1 Error Codes

Sequence	Error Codes	Type	Comments
01	pH OVERLOAD A/C	MAJOR	A = Gas/Standard
02	PO_2 OVERLOAD A	MAJOR	C = Standard C
03	PCO_2 OVERLOAD A	MAJOR	
04	Hct OVERLOAD C	MAJOR	
05	Na^+ OVERLOAD C	MAJOR	
06	K^+ OVERLOAD C	MAJOR	
08	Ca^{++} OVERLOAD C	MAJOR	
10	PROGRAM LOGIC ERR	MAJOR-ALL	-ALL = all electrodes are affected with error codes reported for all electrodes.
11	pH OVERLOAD B/S	MAJOR	B = Gas/Standard B
12	PO_2 OVERLOAD B/S	MAJOR	S = Sample
13	PCO_2 OVERLOAD B/S	MAJOR	
14	Hct OVERLOAD B/S	MAJOR	
15	Na^+ OVERLOAD D/S	MAJOR	D = Standard D
16	K^+ OVERLOAD D/S	MAJOR	
18	Ca^{++} OVERLOAD D/S	MAJOR	
20	CONTROL TABLE ERR	MAJOR-ALL	
21	pH INSTAB A/C	MINOR	INSTAB = Instability
22	PO_2 INSTAB A	MINOR	
23	PCO_2 INSTAB A	MINOR	
24	Hct INSTAB C	MINOR	
25	Na^+ INSTAB C	MINOR	
26	K^+ INSTAB C	MINOR	
28	Ca^{++} INSTAB C	MINOR	
30	MATH ERROR	MAJOR-ALL	
31	pH INSTAB B/S	MINOR	
32	PO_2 INSTAB B/S	MINOR	
33	PCO_2 INSTAB B/S	MINOR	
34	Hct INSTAB B/S	MINOR	
35	Na^+ INSTAB D/S	MINOR	
36	K^+ INSTAB D/S	MINOR	
38	Ca^{++} INSTAB D/S	MINOR	

Table 6.1 Error Codes continued

Sequence	Error Codes	Type	Comments
40	SAMPLER ON ERROR	MAJOR-ALL	-
41	pH SLOPE ERROR	MAJOR	1. flow
42	PO_2 SLOPE ERROR	MAJOR	2. elect maint
43	PCO_2 SLOPE ERROR	MAJOR	3. reversed lines?
44	Hct SLOPE ERROR	MAJOR	
45	Na^+ SLOPE ERROR	MAJOR	
46	K^+ SLOPE ERROR	MAJOR	
48	Ca^{++} SLOPE ERROR	MAJOR	
50	AIR PROGRAM ERROR	MINOR-ALL	- AD's not on at right time
51	E-ZERO DRIFT pH	MAJOR	
52	E-ZERO DRIFT PO_2	MAJOR	± 10mV
53	E-ZERO DRIFT PCO_2	MAJOR	except PO_2
54	E-ZERO DRIFT Hct	MAJOR	
55	E-ZERO DRIFT Na^+	MAJOR	
56	E-ZERO DRIFT K^+	MAJOR	
58	E-ZERO DRIFT Ca^{++}	MAJOR	
60	BY-PASS VALVE BAD	MAJOR	(K) detects
61	pH OUT OF RANGE	MINOR	
62	PO_2 OUT OF RANGE	MINOR	
63	PCO_2 OUT OF RANGE	MINOR	
64	Hct TOO LOW	MINOR	
65	Hct TOO HIGH	MINOR	
66	Na^+ OUT OF RANGE	MINOR	
67	K^+ OUT OF RANGE	MINOR	
69	Ca^{++} OUT OF RANGE	MINOR	
70	Hct CALC ERR, Na	MAJOR-Hct	CALC = Calculation — Na 100-180 mmol
71	A to A DRIFT pH	MAJOR	A to A = Analysis to Analysis
72	A to A DRIFT PO_2	MAJOR	
73	A to A DRIFT PCO_2	MAJOR	
74	A to A DRIFT Hct	MAJOR	
75	A to A DRIFT Na^+	MAJOR	
76	A to A DRIFT K^+	MAJOR	
78	A to A DRIFT Ca^{++}	MAJOR	
80	PO_2 MEMBRANE BAD	MAJOR	DRY CHAMBER then Ø √mem, + flow
81	PCO_2 MEMBRANE BAD	MAJOR	
82	PO_2 MEM OVERLOAD	MINOR	MEM = Membrane
83	PCO_2 MEM OVERLOAD	MINOR	often = math err
85	Δ mVs, AD2	MAJOR-ALL	~ 70 ± 20 typical — Δ min=25 no max
86	Δ mVs, AD3	MAJOR-ALL	~ 40 ± 10 typical
88	FLOW RATE SLOW	MINOR-ALL	-(39-54) for calib
89	FLOW RATE FAST	MINOR-ALL	(-5) to 30 analysis diff from cal time

Table 6.1 Error Codes continued

Sequence Error Codes		Type	Comments
90	NO AIR WHEN REQ	MAJOR-ALL	REQ = Required
91	NO SAMPL WHEN REQ	MAJOR-ALL	
92	NO GAS A WHEN REQ	MAJOR-ALL	
93	NO GAS B WHEN REQ	MAJOR-ALL	
94	NO STD A WHEN REQ	MAJOR-ALL	
95	NO STD B WHEN REQ	MAJOR-ALL	
96	NO STD C WHEN REQ	MAJOR-ALL	
97	NO STD D WHEN REQ	MAJOR-ALL	
98	NO FLUSH WHEN REQ	MAJOR-ALL	
99	VTIM ERROR	MAJOR-ALL	VTIM = Variable Time Command

SYSTEM ERRORS		Type	Comments
A0	AB THERM. OPEN ER	MINOR-ALL	AB = Air Bath
A1	AB THERM. SHORTED	MINOR-ALL	THERM. = Thermistor
A2	AB DAC UPPER LIM	MINOR-ALL	DAC = D/A Converter
A3	AB DAC LOWER LIM	MINOR-ALL	LIM = Limit
A4	AB TEMP. TOO LOW	MINOR-ALL	TEMP. = Temperature
A5	AB TEMP. TOO HIGH	MINOR-ALL	
A6	AB RESPONSE SLOW	MINOR-ALL	
A7	BLOWER MOTOR FAIL	MINOR-ALL	
H0	CLK INT TOO LONG	MINOR-ALL	CLK INT = Clock Interrupt
H1	PROGRAM FAIL ERR	MINOR-ALL	
H2	ADC NOT READY ERR	MINOR-ALL	ADC = Analog-to-Digital Converter
H3	ADC NOT SCANNING	MINOR-ALL	
H4	ADC SCAN ERROR	MINOR-ALL	
H5	BAROMETER FAILURE	MINOR-PO_2 & PCO_2	
P0	PRINTER ERROR?		
P1	PRINTER PGF ERROR		PGF = Program Fail
P2	PRINTER TIMER ERR		
P3	PRINTER WATCHDOG		
P4	PRINTER STACK ERR		
P5	PRINTER CHECKSUM		
P6	PRINTER ANODE ON		
P7	PRINTER ANODE OFF		
P8	PRINTER TIMEOUT		
P9	PRINTER NOT CONN.		CONN. = Connected
S0	SP THERM. OPEN ER	MINOR-ALL	SP = Sample Preheater
S1	SP THERM. SHORTED	MINOR-ALL	
S2	SP DAC UPPER LIM	MINOR-ALL	
S3	SP DAC LOWER LIM	MINOR-ALL	
S4	SP TEMP. TOO LOW	MINOR-ALL	
S5	SP TEMP. TOO HIGH	MINOR-ALL	

6.2 Troubleshooting

Troubleshoot errors by noting the error code and following the appropriate procedure. For multiple errors, the procedures are given in order of effectiveness; therefore, solve errors in this order. Solving errors in this order may eliminate problems that would otherwise require a service call. Refer to Section 6.4.1, the System Test screens, for an explanation of how to access the subassemblies discussed in the following procedures.

> NOTE: After servicing electrodes outside the Analyzer Compartment, allow a 5 minute warm-up period for Na, K, Ca^{++}, or pH electrodes and a 15 minute warm-up period for PCO_2 or PO_2 electrodes.

If these procedures do not solve the problem, contact NOVA Technical Service. When calling NOVA Technical Service for assistance with troubleshooting, it it helpful to have written down the error codes, flow times, and slope performance numbers.

FOR TECHNICAL ASSISTANCE OR SERVICE, CALL TOLL FREE:

1-800-545-NOVA

OR CALL NOVA BIOMEDICAL DIRECT:

1-617-894-0800

6.2.1 Flow-Related Errors -- 88, 89 Flow Rate Slow/Fast, 90 No Air When Required

Flow Error Codes are usually related to blockages or problems with the flow path. If flow times, as read from the System Status screen, are unacceptable (Table 6.2) correct as follows.

Table 6.2 Flow Time Limits (in tenths of seconds)

	Microcomputer Limits
Calibration	39 - 54
Analysis (change from calibration time)	-5 - +30

Possible Cause:	Corrective Procedure:
1. Flow Blockage	1. Flush the Flow Path (Sec. 5.4.6); then aspirate Cleaning Solution (Sec. 5.4.1).
2. Worn W/R Segments	2. Replace the W/R Tubing Segments (Sec. 5.4.11).
3. Incorrect Probe Position	3. Perform Probe Placement Test (Sec. 6.3.1.7) and adjust if needed.
4. Incorrect S Line connection	4. Reseat S Line.
5. Incorrect electrode seal in electrode chamber	5. Insert correct washer in Flow Cell chamber (Secs. 5.4.7, 5.4.8. 5.4.9).
6. Failing Air Detector	6. Perform Air Oscillator Test (Sec. 6.3.1.4) and replace Sample Pre-heater if necessary.

6.2.2 Insufficient Sample

The instrument will abort an analysis cycle and perform a system flush if the sample volume is less than 250 ul.

Possible Cause:	Corrective Procedure:
1. Flow Blockage	1. Flush the Flow Path (Sec. 5.4.6); then aspirate Cleaning Solution (Sec. 5.4.1).
Sample volume insufficient	2. Ensure at least 250 ul sample size. Verify probe tip completely immersed in sample.
3. Incorrect Probe Position	3. Perform Probe Placement Test (Sec. 6.3.1.7) and adjust if needed.
4. Failing Air Detector	4. Perform Air Oscillator Test (Sec. 6.3.1.4) and replace Sample Pre-heater if necessary.
5. Faulty Bypass Valve	5. Perform a Bypass Valve Test (Sec. 6.3.1.9).

6.2.3 85, 86 Air Detector Δ Millivolt Errors

Possible Cause:	Corrective Procedure:
1. Flow Blockage	1. Flush the Flow Path (Sec. 5.4.6); then aspirate Cleaning Solution (Sec. 5.4.1).
2. Protein-coated Air Detectors	2. Aspirate Cleaning Solution (Sec. 5.4.1).
3. Reagent Pack Empty	3. Replace Reagent Pack (Sec 5.4.15).
4. Incorrect Probe Position	4. Perform Probe Placement Test (Sec. 6.3.1.7) and adjust if needed.
5. Failing Air Detector	5. Perform Air Oscillator Test (Sec. 6.3.1.5) and replace Sample Pre-heater if necessary.
6. Faulty Reagent or Septum Harness	6. Replace Reagent (Sec. 5.4.13) or Septum (Sec. 5.4.14) Harness.

6.2.4 80, 81, 82, 83 PO_2, PCO_2 Electrode Membrane Bad and Membrane Overload

These error codes signify a leaking or improperly functioning membrane.

Possible Cause:	Corrective Procedure:
1. Wet Flow Cell chamber	1. Remove the electrode and washer and dry the Flow Cell chamber with a swab. Verify error solution before recalibrating by performing the PO_2 Membrane Test (Sec. 6.3.2.1).
2. Faulty Membrane	2. Remembrane the electrode (PCO_2 - Sec. 5.4.8, PO_2 - Sec. 5.4.9). Verify error solution before recalibrating by performing the PO_2 Membrane Test (Sec. 6.3.2.1).
3. Faulty electrode spring	3. Replace the electrode. Verify error solution before recalibrating by performing the PO_2 Membrane Test (Sec. 6.3.2.1).

6.2.5 1, 5, 6, 8, 11, 15, 16, 18 Calibration and Analysis Electrode Overload -- Na, K, Ca^{++}, pH

An electrode overload is an electrode voltage that is over acceptable limits.

From the READY FOR ANALYSIS screen, perform a calibration as follows:

- pH or Hct Overload - press MENU, 2, 2, ENTER
- Na, K, or Ca^{++} Overload - press MENU, 2, 3, ENTER

If the error code recurs, troubleshoot as follows:

Possible Cause:	Corrective Procedure:
1. Air bubble inside electrode	1. Remove the electrode and with a wrist-snapping motion shake the electrode down to move bubbles to the back of the electrode.
2. Air bubbles in Flow Cell at the electrode tip	2. Perform a Flow Cell conditioning cycle (Sec. 5.4.3).
3. Blocked Reference Electrode	3. Flush the Reference Electrode (Sec. 5.4.6).
4. Faulty Reagent or Septum Harness	4. Replace Reagent (Sec. 5.4.13) or Septum (Sec. 5.4.14) Harness.
5. Faulty S Line connection	5. Reseat S Line.
6. Reagent Pack empty	6. Replace the Reagent Pack (Sec. 5.4.15).
7. Failing electrode	7. Replace and precondition electrode (Sec. 5.4.7).

6.2.6 2, 3, 12, 13 PO_2 & PCO_2 Calibration and Analysis Electrode Overload

An electrode overload is an electrode voltage that is over acceptable limits.

From the READY FOR ANALYSIS screen, press MENU, 2, 1, ENTER to perform a gas calibration. If the error code recurs, troubleshoot as follows:

Possible Cause:	Corrective Procedure:
1. Low Electrolyte Solution	1. If PCO_2 electrode low, refill. If PO_2 low, remembrane (Sec. 5.4.9).
2. Flow Cell chamber wet	2. Remove the electrode and washer and dry the chamber with a swab.
3. Air bubble inside electrode	3. Remove the electrode and with a wrist-snapping motion shake the electrode down, moving bubbles to the back of the electrode.
4. Faulty membrane	4. Perform membrane tests and replace if necessary (PCO_2 - Secs. 6.3.1.2, 5.4.8; PO_2 - Sec. 6.3.1.3, 5.4.9).
5. Failing electrode	5. Replace and condition electrode (PCO_2 - Sec. 5.4.8, PO_2 - Sec. 5.4.9).

6.2.7 4, 14 Hct Calibration and Analysis Overload

An electrode overload is an electrode voltage that is over acceptable limits.

From the READY FOR ANALYSIS screen, perform a calibration by pressing MENU, 2, 2, ENTER. If the error code recurs, troubleshoot as follows:

Possible Cause:	Corrective Procedure:
1. Flow Blockage	1. Flush the Flow Path (Sec. 5.4.6); then aspirate Cleaning Solution (Sec. 5.4.1).
2. Preheater not connected	2. Press Preheater firmly onto the electrical connections.
3. Reagent Pack empty	3. Replace the Reagent Pack (Sec. 5.4.15).
4. Protein-coated Air Detectors	4. Aspirate Cleaning Solution (Sec. 5.4.1).
5. Faulty Preheater	5. Replace Preheater (Sec. 5.4.18).
6. Faulty Reagent Line	6. Replace Septum and Reagent Harnesses (Secs. 5.4.14, 5.4.15).

6.2.8 41, 45, 46, 48 Na, K, Ca^{++}, pH Slope Errors

Possible Cause:	Corrective Procedure:
1. Air bubble inside electrode	1. Remove the electrode and with a wrist-snapping motion shake the electrode down to move bubbles to the back of the electrode.
2. Air bubbles in Flow Cell at electrode tip	2. Perform a Flow Cell conditioning cycle (Sec. 5.4.3).
3. Unconditioned electrode	3. Condition as follows: • Na - Perform conditioning cycle (Sec. 5.4.2). • K, Ca^{++}, pH - Condition per preconditioning instructions (Sec. 5.4.7).
4. Faulty washer	4. Replace washer (Sec. 5.4.7)
5. Worn W/R Segments	5. Replace Segments(Sec. 5.4.11).
6. Reference electrode - if slope errors on all electrodes	6. Flush the reference electrode, replace and recalibrate. If errors recur, replace Reference Electrode (Secs. 5.4.6, 5.4.10).
7. Electrode cable plugged into incorrect socket on Rack Assembly	7. Ensure electrode cable plugged into correct socket.
8. Failing electrode	8. Replace and precondition electrode (Sec. 5.4.7).
9. Contaminated Reagent Pack	9. Replace Reagent Pack (Sec. 5.4.15).
10. Flow Blockage	10. Flush the Flow Path (Sec. 5.4.6); then Aspirate Cleaning Solution (Sec. 5.4.1).

6.2.9 44 Hct Slope Error

Possible Cause:	Corrective Procedure:
1. Protein-coated Air Detectors	1. Aspirate Cleaning Solution (Sec. 5.4.1).
2. Flow Blockage	2. Flush the Flow Path (Sec. 5.4.6); then Aspirate Cleaning Solution (Sec. 5.4.1).
3. Preheater not connected	3. Seat Preheater firmly on electrical connections.
4. Faulty Preheater	4. Replace Preheater (Sec. 5.4.18).
5. Reagent Pack Empty	5. Replace Reagent Pack (Sec 5.4.15).
6. Faulty Reagent of Septum Harness	6. Replace Reagent (Sec. 5.4.13) or Septum Harness (Sec. 5.4.14).

2.10 42, 43 PO_2, PCO_2 Slope Errors

Possible Cause:	Corrective Procedure:
1. Incorrect Gas Cal values	1. Set correct gas values (Sec. 5.1.8).
2. Reversed gas line hook-up.	2. Ensure gas lines hooked up to correct ports (Sec. 5.4.23).
3. Gases not primed through system.	3. Perform a gas prime (Sec. 5.1.6).
4. Low Electrolyte Solution	4. For: • PCO_2 - refill (refer to Sec. 5.4.8). • PO_2 - remembrane (Sec. 5.4.8).
5. Unconditioned electrode	5. Condition as follows: • PCO_2 - Condition per conditioning instructions (Sec. 5.4.8). • PO_2 - If slope performance number is less than -7, polish in addition to preconditioning (Sec. 5.4.9).
Faulty washer	6. Replace washer (Secs. 5.4.8 & 9)
Failing electrode	7. Replace and condition electrode (PCO_2 - Sec. 5.4.8, PO_2 - Sec. 5.4.9).
8. Empty gas cylinders	8. Replace gas cylinders (Sec. 5.4.23).

6.2.11 21 - 26, 28, 31 - 36, 38 Instability

Possible Cause:	Corrective Procedure:
1. Air bubbles in Flow Cell at the electrode tip	1. Perform a Flow Cell conditioning cycle (Sec. 5.4.3).
2. Unconditioned electrode	2. Condition as follows: • Na - Perform conditioning cycle (Sec. 5.4.2). • K, Ca^{++}, pH - Condition per preconditioning instructions (Sec. 5.4.7). • PCO_2 - Condition per preconditioning instructions (Sec. 5.4.8). • PO_2 - If slope performance number is less than -7, polish in addition to preconditioning (Sec. 5.4.9).
3. Flow Blockage	3. Flush the Flow Path (Sec. 5.4.6); then Aspirate Cleaning Solution (Sec. 5.4.1).
4. Failing electrode	4. Replace and precondition electrode (Sec. 5.4.7).
5. Blocked Reference Electrode (instability errors on all electrodes)	5. Flush the Reference Electrode , replace and recalibrate. If errors recur, replace Reference Electrode (Secs. 5.4.6 & 5.4.10).
6. Worn W/R Segments	6. Replace Segments (Sec. 5.4.11).
7. Faulty Reagent or Septum Harness.	7. Replace the Reagent (Sec. 5.4.13) or Septum (Sec. 5.4.14).
8. Reagent Pack empty	8. Replace the Reagent Pack (Sec. 5.4.15).

6.2.12 51, 55, 56, 58, 71, 75, 76, 78 Na, K, Ca^{++}, pH E-Zero and A to A Drift

E-Zero (Sec 8.2.2) and A to A (Analysis to Analysis) Drift errors are commonly eliminated by performing the appropriate subsystem calibration and reanalyzing the sample. These steps set new calibration standard values which are in closer agreement to the analysis standard values. Perform this procedure as follows:

1. From the READY FOR ANALYSIS screen, press MENU, 2, to access the Maintenance menu. If the error code occurred for the Na, K, or Ca^{++} electrodes, press 3 to select an electrolyte subsystem calibration. If the error code occurred for the pH electrode, press 2 to select a pH/Hct subsystem calibration.
2. Press ENTER to perform the calibration.
3. Analyze the sample per the appropriate analysis procedure (Sec. 3.1.2).

If the error code recurs, troubleshoot as follows:

Possible Cause:	Corrective Procedure:
1. Air bubbles in Flow Cell at electrode	1. Perform a Flow Cell conditioning cycle (Sec. 5.4.3).
2. Unconditioned electrode	2. Condition as follows: • Na - Perform conditioning cycle (Sec. 5.4.2). • K, Ca^{++}, pH - Condition per preconditioning instructions (Sec. 5.4.7).
3. Flow Blockage	3. Flush the Flow Path (Sec. 5.4.6); then Aspirate Cleaning Solution (Sec. 5.4.1).
4. Failing electrode	4. Replace and precondition electrode (Sec. 5.4.7).
5. Reference Electrode - if drift errors on all electrodes	5. Flush the Reference Electrode, replace and recalibrate. If errors recur, replace Reference Electrode (Secs. 5.4.6, 5.4.10).

6.2.13 52, 53, 72, 73 PO_2, PCO_2 E-Zero and A to A Drift

E-Zero (Sec 8.2.2) and A to A (Analysis to Analysis) Drift errors are commonly eliminated by performing the appropriate subsystem calibration and reanalyzing the sample. These steps set new calibration standard values which are in closer agreement to the analysis standard values. Perform this procedure as follows:

1. From the READY FOR ANALYSIS screen, press MENU, 2, 1 ENTER to perform a gas subsystem calibration.
2. Analyze the sample per the appropriate analysis procedure (Sec. 3.1.2).

If the error code recurs, troubleshoot as follows:

Possible Cause:	Corrective Procedure:
1. Low Electrolyte Solution	1. Correct as follows: • $\underline{PCO_2}$ - refill (refer to Sec. 5.4.8). • $\underline{PO_2}$ - remembrane (Sec. 5.4.9).
2. Faulty membrane	2. Perform membrane tests (PCO_2 - Sec. 6.3.1.2, PO_2 - Sec. 6.3.1.3).
3. Unconditioned electrode	3. Condition as follows: • $\underline{PCO_2}$ - Condition per conditioning instructions (Sec. 5.4.8). • PO_2 - If slope performance number is less than -7, polish in addition to preconditioning (Sec. 5.4.9).
4. Failing electrode	4. Replace and condition electrode (PCO_2 - Sec. 5.4.8, PO_2 - Sec. 5.4.9).
5. Empty gas cylinders	5. Replace gas cylinders (Sec. 5.4.23).

6.2.14 61 - 67, 69 pH, PO_2, PCO_2, Hct, Na, K, Ca^{++} Out of Range

The sample results are not within the measurement range of the instrument.

6.2.15 90 - 98 No Standards, Sample, Gas, Air When Required

The system does not detect fluid or gas at the proper position at the proper time. An abort flush sequence will immediately occur.

Possible Cause:	Corrective Procedure:
1. Standard or Gas empty	1. Replace Reagent Pack (Sec. 5.4.15) or Gas cylinder (Sec. 5.4.23).
2. Flow Blockage	2. Flush the Flow Path (Sec. 5.4.6); then Aspirate Cleaning Solution (Sec. 5.4.1).
3. Improper gas delivery	3. Verify gas regulator adjustment at 5 PSI (Sec. 5.4.23).
4. Faulty Harness	4. Replace Harness as follows: • W/R - Sec. 5.4.12 • Reagent - Sec. 5.4.13 • Septum - Sec. 5.4.14
5. Incorrect Probe position	5. Perform Probe Placement Test (Sec. 6.3.1.7) and adjust if needed.
6. Faulty Air Detectors	6. Troubleshoot per Air Detector Millivolt Errors (Sec. 6.2.3).

6.2.16 60 Bypass Valve Failure

Perform the Pump Bypass Valve test (Sec. 6.3.1.10). Contact NOVA Technical Service if the valve is defective.

6.2.17 70 Hct Calculation Error

The sodium concentration of the sample (used in calculating hematocrit), is outside allowable range because of high sample concentration or sodium error.

6.2.18 10 Program Logic, 20 Control Table, 30 Math, 40 Sampler On, 50 Air Program, 99 VTIM Errors

If error code 40, SAMPLER ON, occurs, the sampler has not returned to the home position in the time allowed. Repeat the operation that caused the error code. If the code recurs, contact Technical Service.

For the other error codes, contact Technical Service.

6.2.19 System Errors

To eliminate a System Error Code, press 0 and the error code will disappear from the screen. If the error code is detected again it will reappear on the screen. An A4 or A5 (AB Temp. Too High/Low) error code will occur during normal operation. If any System error code (other than routine A4 or A5 codes) continually reappears, contact NOVA Technical Service.

6.2.20 Unacceptable Results on Aqueous Controls — Na, K, Ca^{++}, pH

Possible Cause:	Corrective Procedure:
1. Air bubbles in Flow Cell at the electrode tip	1. Perform a Flow Cell conditioning cycle (Sec. 5.4.3).
2. Calibration points approaching range limits.	2. Press CAL, ENTER to recalibrate.
3. Unconditioned Electrode	3. Condition as follows: • Na - Perform conditioning cycle (Sec. 5.4.7). • K, Ca^{++}, pH - Condition per preconditioning instructions (Sec. 5.4.7).
4. Faulty washer	4. Replace washer (Sec. 5.4.7)
5. Failing electrode	5. Replace and precondition electrode (Sec 5.4.7).
6. Worn W/R segments	6. Replace W/R segments (Sec. 5.4.11).
7. Blocked Reference Electrode	7. Flush the Reference Electrode (Sec. 5.4.6).
8. Contaminated Reagent Pack	8. Replace the Reagent Pack (Sec. 5.4.15).
9. Contaminated Aqueous Controls	9. Visually check for signs of bacterial growth. Do not use if turbid or discolored.

6.2.21 Unacceptable Results on Aqueous Controls -- PCO_2, PO_2

Possible Cause:	Corrective Procedure:
1. Incorrect Cal Gas values	1. Set correct gas values (Sec. 5.1.8).
2. Air bubbles in Flow Cell at the electrode tip	2. Perform a Flow Cell conditioning cycle (Sec. 5.4.3).
3. Air bubble inside electrode	3. Remove the electrode and with a wrist-snapping motion shake the electrode down, moving bubbles to the back of the electrode.
4. Low Electrolyte Solution	4. Correct as follows: • PCO_2 - refill (refer to Sec. 5.4.8). • PO_2 - remembrane (Sec. 5.4.9).
5. Faulty washer	5. Replace washer (Secs. 5.4.8 & 9)
6. Calibration points approaching range limits.	6. Press CAL, ENTER to recalibrate.
7. Unconditioned electrode	7. Condition as follows: • PCO_2 - Condition per conditioning instructions (Sec. 5.4.8). • PO_2 - If slope performance number is less than -7, polish in addition to preconditioning (Sec. 5.4.9).
8. Failing electrode	8. Replace and condition electrode (PCO_2 - Sec. 5.4.8, PO_2 - Sec. 5.4.9).
9. Contaminated Aqueous Controls	9. Visually check for signs of bacterial growth. Do not use if turbid or discolored.

6.2.22 Unacceptable Results on Aqueous Controls -- Hct

Possible Cause:	Corrective Procedure:
1. Protein-coated Air Detectors	1. Aspirate Cleaning Solution (Sec.5.4.1).
2. Incorrect Na value	2. Perform the Unacceptable Results on Aqueous Controls -- Na, K, Ca^{++}, pH troubleshooting procedure (Sec. 6.2.20).
3. Contaminated Aqueous Controls	3. Visually check for signs of bacterial growth. Do not use if turbid or discolored.

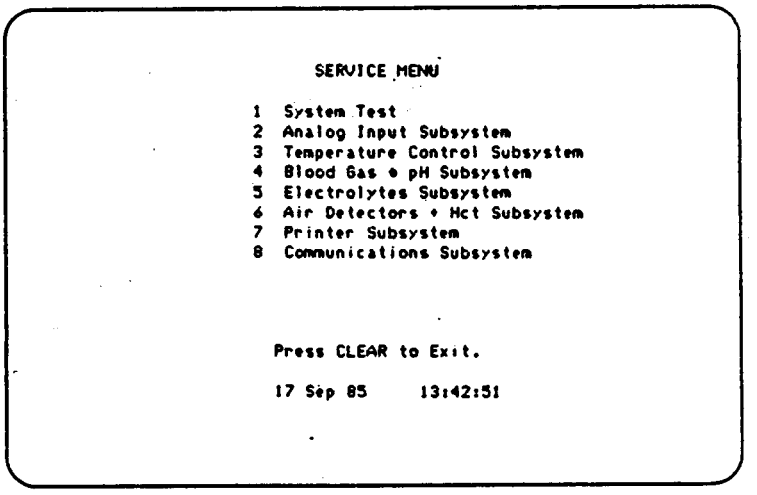
6.3 Service Menu

The Service menu contains screens to:

- Manually operate the mechanical subassemblies of the instrument
- Obtain temperature information and millivolt information for all electrode and analog channels
- Troubleshoot the instrument

Access the Service menu as follows:

1. From the READY FOR ANALYSIS screen, press MENU to access the MAIN MENU screen.
2. Press 3, accessing the SERVICE MENU screen.
3. See Sections 6.3.1 to 6.3.8 to perform the appropriate servicing. If you wish to exit any service function, press CLEAR to return to the SERVICE MENU screen. Press CLEAR again to return to the MAIN MENU screen. Press CLEAR once more to return to READY (NOT READY) FOR ANALYSIS screen.



SERVICE MENU

6.3.1 System Test

The System Test screens are used to test the electrode and mechanical subsystems of the STAT PROFILE 1. Following an explanation of how to access the Subsystem Test screens, Sections 6.3.1.1 - 6.3.1.10 explain how to use the screen functions in the electrode and mechanical subsystem tests.

NOTE: Accessing functions in the System Test screens will cause a 30 minute flush or autocalibration cycle delay. Reinitializing the accessed functions, or exiting the system test screens, will cancel the delay. This 30 minute cycle delay feature is used during maintenance to stop unwanted fluid and gas flow.

6.3.1.1 System Test Functions

Access the System Test screens as follows:

1. From the SERVICE MENU, press 1 to access the System Test 1 screen. The SYSTEM TEST 1 screen displays multiple millivolt readings for electrodes and air detectors at the top of the screen, in addition to displaying the system test functions.

```
SYSTEM TEST #1          VER  2          REV  10

pH    - 044.08   Na+    -008.53   AD2    +0016.60
PCO2  -0116.90   K+     -011.89   AD3    -0003.90
PO2   • 074.77   Ca++   -023.04   BP     +0761.80

1  Millivolt Display        Multiple    Single
2  PCO2 Membrane            Off         On
3  PO2 Gain                 Low         Hi
4  Air Oscillators          0 - Off
5  Pump                     0 - Off
6  Sampler Position         0
7  Valve Position           1
8  Gas                      0 - Off
9  Pump Bypass Valve        Closed      Open

                Press CLEAR to Exit.
```

SYSTEM TEST 1

2. To monitor a single analog channel continuously, the System Test Screen exists in a second form. The SYSTEM TEST 2 screen, which is accessed from the SYSTEM TEST 1 screen, displays mV readings from 1 of 32 channels. Press 1 to change the millivolt display to the SYSTEM TEST 2 screen, as shown below.

```
SYSTEM TEST #2      Ver  1      Rev  0

CHANNEL 1                  - 008.61

Press ENTER to Advance Channel Number.

1  Millivolt Display        Multiple    Single
2  PCO2 Membrane            Off    On
3  PO2 Gain                 Low    Hi
4  Air Oscillators          0-Off
5  Pump                     0-Off
6  Sampler Position         0
7  Valve Position           1
8  Gas                      0-Off
9  Pump Bypass Valve        Closed      Open

                Press CLEAR to Exit.
```

SYSTEM TEST 2

   To move to higher channel numbers, press ENTER repeatedly. To move to lower channel numbers, press . repeatedly.
3. Perform the appropriate subsystem test as in Section 6.3.1.2 - 6.3.1.10.
4. To exit the SYSTEM TEST screens, press CLEAR to return to the SERVICE MENU screen. Press CLEAR again to return to the MAIN MENU screen. Press CLEAR once more to return to READY (NOT READY) FOR ANALYSIS screen.

ERR INSTAB/OVERLOAD

6.3.1.2 Shorting Strap Test

The Shorting Strap Test helps to distinguish an electrode problem as either a system electronics or electrode problem.

1. Open the Analyzer Compartment door.
2. Disconnect the electrode and Flow Cell cables from the Electrode Rack assembly.

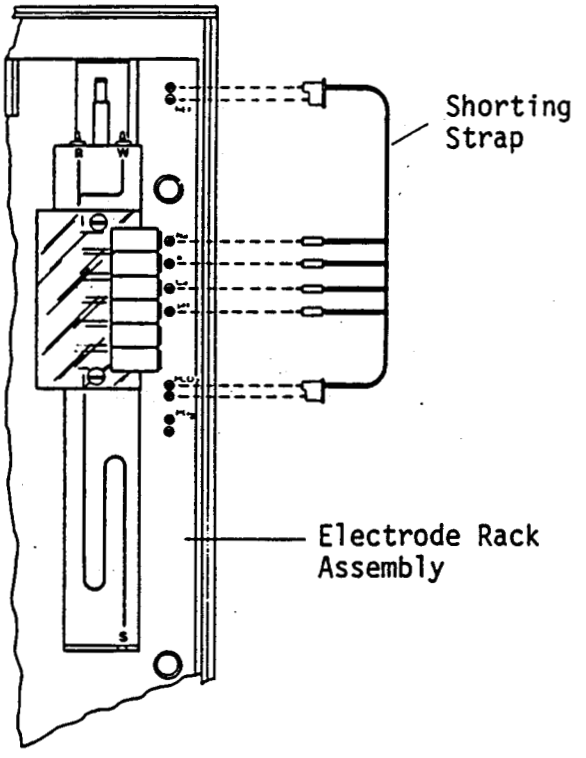


Figure 6.1 Placement of Shorting Strap

> **CAUTION:** Do not plug the Shorting Strap into the PO_2 socket; damage will occur.

3. Plug the shorting strap into the Electrode Rack assembly as shown in Figure 6.1.
4. Press CAL, ENTER. Ignore all error codes, except for instability codes. If any of these error codes are displayed, contact Technical Service.
5. The millivolt readings at the top of the screen should stay between -2.0 and +2.0 mV for Na, K, Ca^{++}, pH, and PCO_2. If any readings are outside this range, contact Technical Service.
6. Unplug the shorting strap. Connect the electrode and flow cell cables to the Electrode Rack assembly.
7. Wait five minutes then press CAL, ENTER. After the first calibration is finished, press CAL, ENTER again.

6.3.1.3 PCO_2 Membrane Test

This test checks for leaks in the PCO_2 membrane. The mV reading across the membrane will identify the presence of a leak.

1. Press MENU, 3, 1, 6, 1, 5, 4 to aspirate flush solution into the flow path.
2. After 5 seconds press 5, 0, 6, 0 to stop aspiration.
3. Press 1, accessing the System Test 2 screen.
4. Press ENTER or . repeatedly to move the millivolt display to channel 10.
5. With the fluid in the flow path, observe channel 10 for the membrane voltage value (the membrane detector is Off). Note this value.
6. Press 2, turning the membrane detector On and observe the membrane voltage. The absolute value difference from Off should be within 100 millivolts. If the difference is less than 100 mV, the membrane is not leaking (do not continue with Steps 7 & 8). If the difference is greater than 100 millivolts, continue with Step 7.
7. Remove the electrode and dry the washer, Flow Cell chamber, and electrode (being careful not to touch the membrane). Press 2 to turn the membrane detector Off and repeat steps 4 - 7. If the difference is still greater than 100 millivolts, continue with Step 8.
8. Remove the electrode and remembrane per Section 5.4.7. Repeat the test to verify membrane integrity.

6.3.1.4 PO_2 Gain

PO_2 Gain, function 3 in the System Test screens, is for service representative use. It is also used as a convenient System Test function for delaying flush and autocalibration cycles (See note, Sec. 6.3.1).

6.3.1.5 Air Oscillator and Air Detector Test

By turning the Air Oscillators on and off, you can determine if there is a malfunction in an Air Oscillator circuit, or if the Air Detectors (located in the flow path) have excess protein coating.

1. Press MENU, 3, 1, 6, 1, 5, 4 to aspirate flush solution into the flow path. After about 5 seconds press 5, 0, 6, 0 to shut off the pump and return the probe to the home position.
2. Press 4 to access the air oscillator function. The options are:

   0 - Off (Air Detectors Off)
   1 - Low (Air Detectors 2 & 3 On)
   2 - High (Unused Air Detector On)
   3 - All (All Air Detectors On)

3. Note the mV values with the air detectors Off.
4. Press 1 to turn the air detectors On.
5. The mV reading in the On position should be less than 400 millivolts on all air detectors. If the millivolts are greater than this, clean the flow path with Cleaning Solution per section 5.4.2.

6.3.1.6 Pump Test

The pump test sequence is controlled by the System test screen. The pump has 4 speeds which can be changed manually.

1. Press 5, displaying all 5 speeds next to the pump function. (The current state of the pump is shown before pressing 5.) These speeds are:

   0 - Off
   1 - Low
   2 - MLo
   3 - MHi
   4 - High

2. Press 0. The sampler pump should not operate.
3. Press 5, 1. The pump operates at LOW speed.
4. Press 5, 2. The pump operates at MEDIUM LOW speed.
5. Press 5, 3. The pump operates at MEDIUM speed.
6. Press 5, 4. The pump operates at HIGH speed.
7. Press 0 to turn the pump off.

6.3.1.7 Sampler Probe Position Test

The ten Sampler Probe positions (Figure 6.2) are monitored by a solid state optical detector on the Sampler board. The detector consists of an infrared emitter and an infrared light detector. When a position flag blocks the emitter/detector junction, the microcomputer interprets this as home position (position 0) for the Sampler Probe. All other sampler positions are then "found" by a stepper motor which steps the probe to the proper position. The System Test sampler position function allows manual control of the sampler from the 0 position (fully retracted) through position 9, the sample aspiration position (fully extended).

> CAUTION: Do not open or close the Analyzer Compartment door when the sampler probe is in position 9. Probe damage will occur.

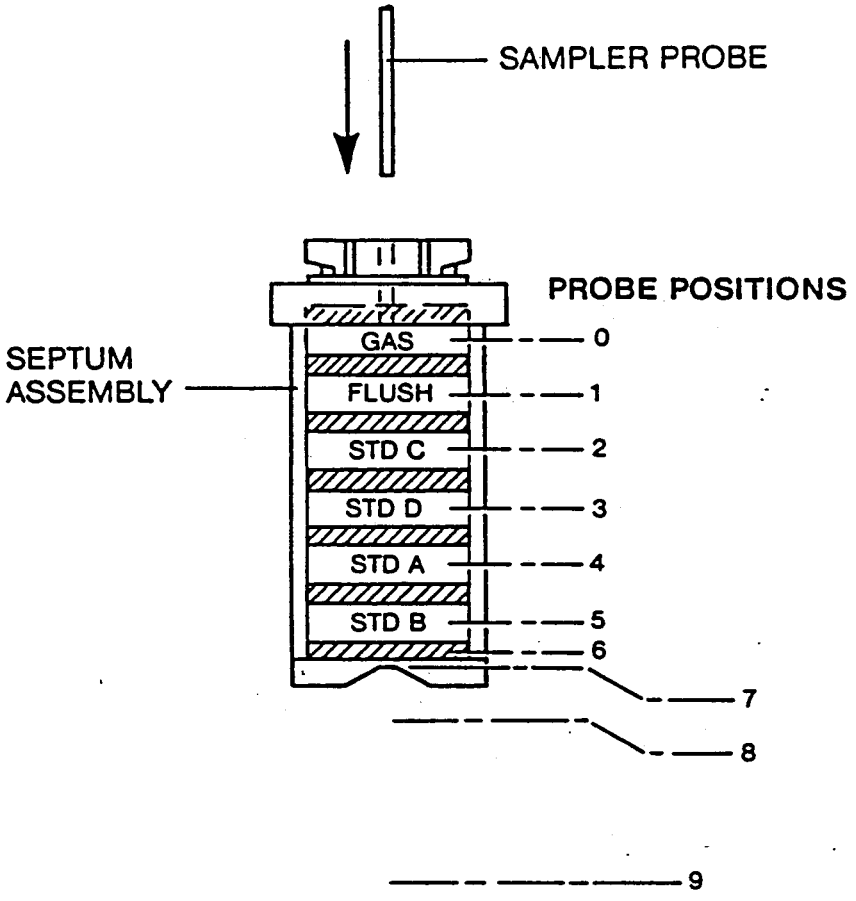


Figure 6.2 Sampler Probe Positions

1. Press 6, displaying all 10 options next to the Sampler function. (The current state of the Sampler is shown before pressing 6.)
2. Press 0. The Sampler Probe does not move (Gas position).
3. Press 6, 1. The Sampler Probe moves DOWN to position 1 (Flush).
4. Press 6, 2. The Sampler Probe moves DOWN to position 2 (Std. C).
5. Press 6, 3. The Sampler Probe moves DOWN to position 3 (Std. D).
6. Press 6, 4. The Sampler Probe moves DOWN to position 4 (Std. A).
7. Press 6, 5. The Sampler Probe moves DOWN to position 5 (Std. B).
8. Press 6, 6. The Sampler Probe moves DOWN to position 6 (Probe tip is buried in the bottom septum of the Septum Assembly).
9. Press 6, 7. The Sampler Probe moves DOWN to position 7 (Probe tip is just visible in the depression at the bottom of the Septum Assembly).
10. Press 6, 8. The Sampler Probe moves DOWN to position 8 (probe tip extends 3/8 inch (9 mm) out of septum retainer.
11. Press 6, 9. The Sampler Probe moves DOWN to position 9 (probe tip extends 1-1/2 inch (38 mm) out of septum assembly for sample aspiration.
12. Press 6, 0. The Sampler Probe moves UP to position 0, the home position.
13. Perform the Probe Septum Assembly placement test as follows.

Probe Placement Test

Proper Probe position in the Septum Assembly is critical for error-free reagent delivery and analysis. Verify proper probe position as follows.

1. Press 6, 9 from the System Test 1 screen, to move the probe to position 9.

> CAUTION: Do not open or close the Analyzer Compartment door when the probe is in position 9. Probe damage will occur.

2. Slide the probe adjustment tool (Figure 6.3) over the probe and hold it firmly to the base of the sampler assembly so that the probe tip extends toward the stepped end. The probe tip should be lower than the high step but not lower than the low step. If the probe tip is not between these 2 surfaces, adjust as follows.

Probe Position Adjustment

1. Press 6, 9 from the System Test 1 screen, to move the probe to position 9.
2. Using a phillips head screwdriver, loosen the screw which holds the Sampler Adjustment Plate to the Instrument (see Figure 6.3).

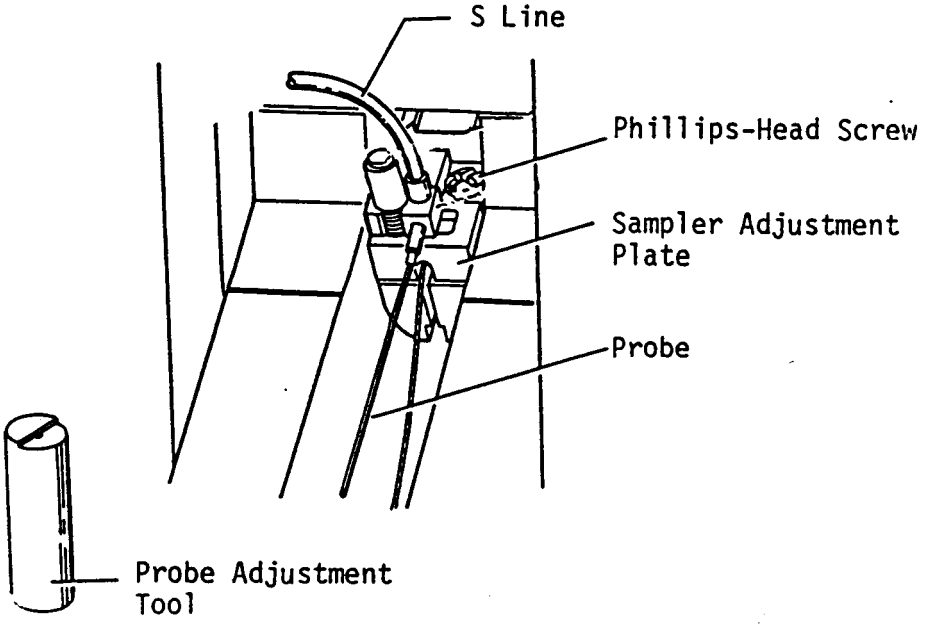


Figure 6.3 Probe Adjustment

3. Advance the plate (and the probe) up or down as needed, based on the observed maladjustment.

4. Tighten the screw holding the probe secure.
5. Verify that the probe tip is positioned between the 2 steps. If positioning is unsatisfactory, repeat procedure.
6. Press 6, 0 to return the probe to the home position.

6.3.1.8 Valve Test

The Pinch Valve contains 4 tubing pinch stations which are controlled by a motor-driven cam. The Valve regulates the flow of standards A, B, C, and D from the Reagent Pack. Although there are only 4 valve positions, the motor can move the cam in the "forward" or the "reverse" direction. To allow for testing the Valve in both directions, the function numbers 1 through 8 are used to specify the Valve position: 1 through 4 specify the corresponding positions in the forward direction, and 5 through 8 specify positions 1 through 4 in the reverse direction.

1. Press 7 from the System Test 1 screen, displaying the 8 valve options (see Figure 6.4).

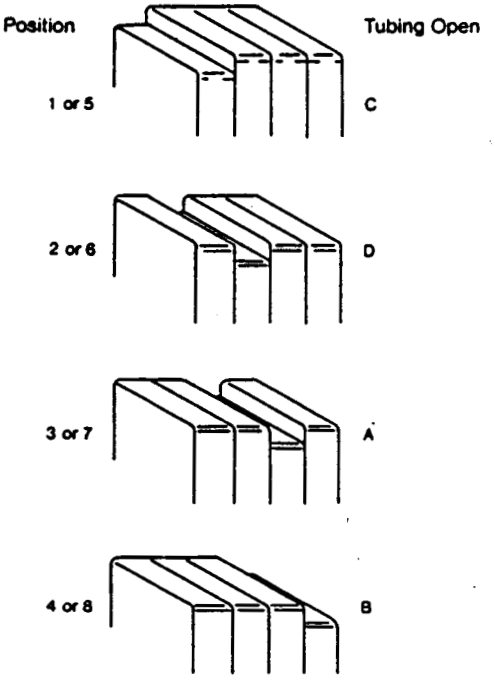


Figure 6.4 Valve positions

2. Press 1. The motor does not move, and the valve stays in position 1.
3. Press 7, 2. The motor moves in the forward direction, moving the valve to position 2.
4. Press 7, 3. The motor moves in the forward direction, moving the valve to position 3.

4. Press 7, 4. The motor moves in the forward direction, moving the valve to position 4.
5. Press 7, 5. The motor moves in the reverse direction, moving the valve to position 1.
6. Press 7, 6. The motor moves in the reverse direction, moving the valve to position 2.
7. Press 7, 7. The motor moves in the reverse direction, moving the valve to position 3.
8. Press 7, 8. The motor moves in the reverse direction, moving the valve to position 4.
9. Press 7, 1. The motor move in the forward direction, moving the valve to position 1, the idle position.

6.3.1.9 Gas Test

The Gas function allows manual control of the flow of Cal gas A and Cal gas B at low, medium, and high pumping rates. Test the gas pump sequence as follows.

> CAUTION: The Pump Bypass Valve must always be opened when the gas is manually pumped (Step 2 below and see 6.3.1.10). If gas is pumped without the Pump Bypass Valve open, damage can occur.

1. Press 8, displaying the 6 flow rates next to the gas function. (The current state of gas flow is shown before pressing 8). The flow rate options for Gas are as follows:

   0 - Off
   1 - Cal gas A low
   2 - Cal gas A medium
   3 - Cal gas A high
   4 - Cal gas B low
   5 - Cal gas B medium
   6 - Cal gas B high

2. Press 9 to open the Pump Bypass Valve.
3. Press 8, displaying the seven gas choices.
4. Press 0. The gas should be off.
5. Press 8, 1. Gas A should bubble through the humidifier at a slow rate.
6. Press 8, 2. Gas A should bubble through the humidifier at a medium rate.
7. Press 8, 3. Gas A should bubble through the humidifier at a fast rate.
8. Press 8, 4. Gas B should bubble through the humidifier at a slow rate.
9. Press 8, 5. Gas B should bubble through the humidifier at a medium rate.
10. Press 8, 6. Gas B should bubble through the humidifier at a fast rate.
11. Press 8, 0 to shut off the gas.
12. Press 9 to close the Pump Bypass Valve.

6.3.2 Subsystem Test Analog Input

This screen displays 24 analog channels of real time mV activity (Channel 21 continuously cycles through 4 of its 8 available channels). These channels are useful for advanced troubleshooting.

Access the analog input as follows:

1. From the Service Menu, Press 2, accessing the SUBSYSTEM TEST ANALOG INPUT screen.
2. Press CLEAR, CLEAR, CLEAR to return to the READY FOR ANALYSIS screen.

SUBSYSTEM TEST ANALOG INPUT

Channel	mV	Channel	mV
0	+000.04	12	-0001.40
1	-139.79	13	+0775.20
2	-017.39	14	+ 100.15
3	+000.15	15	- 100.16
4	+009.80	16	+0021.60
5	+069.74	17	+0036.10
6	-0261.80	18	-0004.80
7	+058.18	19	+0052.70
8	+0694.80	20	+0004.00
9	+0669.80	21.0	-0034.50
10	+1011.70	22	+0022.10
11	-0014.00	23	• 002.09

Press CLEAR to Exit.

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SUBSYSTEM TEST ANALOG INPUT

6.3.2.1 PO_2 Membrane Test

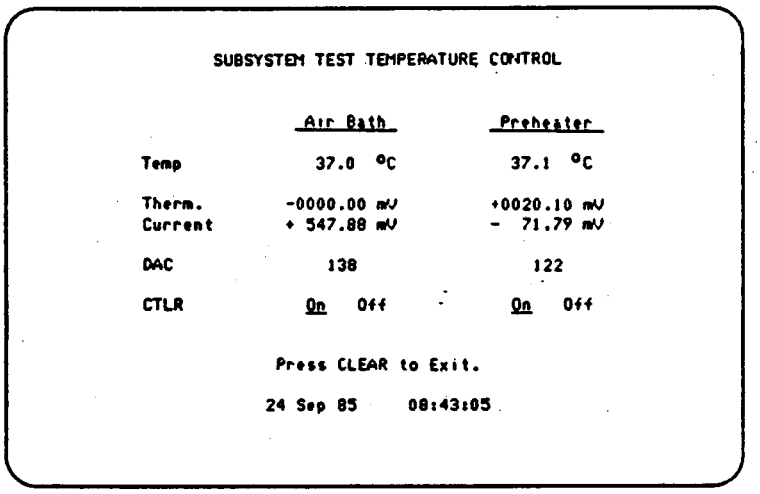
This test checks the PO_2 membrane for current leakage. It is helpful for diagnosing PO_2 problems.

1. From the Service Menu, Press 2, accessing the SUBSYSTEM TEST ANALOG INPUT screen.
2. Observe the millivolt reading on analog channel 8. This is the input voltage for the oxygen electrode.
3. Observe the millivolt reading on analog channel 9. This is the output voltage for the oxygen electrode.
4. The observed millivolt reading on analog channel 8 should be no greater than 50 millivolts above channel 9. If it is greater, a current leakage is occurring within the electrode.
5. If electrode fails the test, remove the electrode, clean the Flow Cell chamber, and remembrane the electrode.

6.3.3 Subsystem Test Temperature Control

This screen allows you to observe instrument temperature readings. It is used by the service representative for system diagnostics. Observe the instrument temperature as follows:

1. From the Service Menu, press 3, accessing the SUBSYSTEM TEST TEMPERATURE CONTROL screen.
2. Press CLEAR to leave this screen.



SUBSYSTEM TEST TEMPERATURE CONTROL

6.3.4 Subsystem Test Blood Gases + pH

This screen allows you to check:

- Stability of the PO_2, PCO_2, and pH electrode readings during analysis and calibration as shown by the Stability (Stab) Factors. Significant increases in the factors (towards the high single numbers) indicate that electrode maintenance is needed.
- Millivolt readings for the last calibration and the last analysis.
- Drift from the calibration value.
- Results (Conc) of the last analysis.
- Slope Performance Numbers for the last calibration. The Slope Performance Limits are as Table 6.3:

Table 6.3 Blood Gases and pH Slope Performance Number Limits

pH	9.0 - 10.5
PCO_2	7.9 - 11.3
PO_2	-2.0 - -7.0

This screen is useful for diagnosing a poorly performing electrode. Access this screen as follows:

1. From the Service Menu, press 4, accessing the SUBSYSTEM TEST BLOOD GASES + pH screen.
2. Press CLEAR to leave this screen.

SUBSYSTEM TEST BLOOD GASES + pH

	Gas B/Std B mV	Gas B/Std B Stab	Gas A/Std A mV	Gas A/Std A Stab	Slope
pH	- 21.6	0.4	- 53.3	0.4	+10.1
PCO_2	+ 127.6	0.6	+ 111.3	1.3	+ 9.3
PO_2	- 4.0	0.0	- 244.1	0.0	- 4.0

	Sample mV	Sample Stab	Gas A/Std C mV	Gas A/Std C Stab	Conc
pH	- 64.7	0.4	- 57.1	0.4	7.568
PCO_2	+ 91.9	0.9	+ 110.5	8.3	18.8
PO_2	- 228.4	0.0	- 231.5	0.0	155.1

Press CLEAR to Exit.
18 Jun 85 9:57:22

6.3.5 Subsystem Test Electrolytes

This screen is useful for diagnosing a poorly performing electrode, allowing you to check:

- Stability of Na, K, and Ca^{++} electrode readings during analysis and calibration as shown by the Stability (Stab) Factors. Significant increases in the factors (towards the high single numbers) indicate that electrode maintenance is needed.
- Millivolt readings for the last calibration and the last analysis.
- Drift from the calibration value.
- Results (Conc) of the last analysis.
- Slope Performance Numbers for the last calibration. The Slope Performance Limits are as Table 6.4:

Table 6.4 Electrolyte Slope Performance Number Limits

Na	9.0 - 10.7
K	8.8 - 10.9
Ca^{++}	8.9 - 11.6

Access this screen as follows:

1. From the Service Menu, press 5, accessing the SUBSYSTEM TEST ELECTROLYTES screen.
2. Press CLEAR to leave this screen.

SUBSYSTEM TEST ELECTROLYTES

	Std-D mV	Std-D Stab	Std-C mV	Std-C Stab	Slope
Na+	- 26.0	0.4	- 10.3	14.5	+ 9.4
K+	- 28.8	0.4	- 11.9	3.4	+10.1
Ca++	- 2.5	0.5	- 5.9	3.5	+11.0

	Sample mV	Sample Stab	Std-C mV	Std-C Stab	Conc
Na+	- 11.6	3.0	- 6.7	1.0	115.2
K+	- 29.1	0.4	- 11.1	0.5	1.91
Ca++	- 13.5	0.4	- 5.9	1.0	0.56

Press CLEAR to Exit.

18 Jun 85 9:57:22

6.3.6 Subsystem Test Air Detectors + Hct

This screen is useful for diagnosing a poorly performing air detector, allowing you to check:

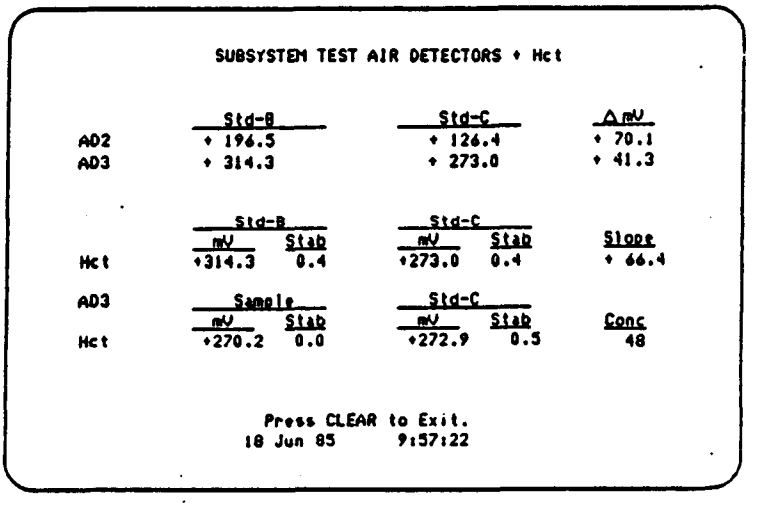
- Air detector millivolt differences on calibration.
- Millivolt readings for the last calibration and the last analysis for the Hct Impedance electrode.
- Stability of the Hct Impedance electrode both on last analysis and last calibration as shown by the Stability (Stab) Factor. A significant increase in the factor (towards the high single numbers) indicates that electrode maintenance is needed.
- Drift from the calibration value for the Hct Impedance electrode.
- Results (Conc) of the last analysis.
- Slope Performance Numbers for the last calibration. The Slope Performance Limits are as Table 6.5:

Table 6.5 Hematocrit Slope Performance Number Limits

Hct 45.0 - 98.0

Access this screen as follows:

1. From the Service Menu, press 6, accessing the SUBSYSTEM TEST AIR DETECTORS + Hct screen.
2. Press CLEAR to leave this screen.



SUBSYSTEM TEST AIR DETECTORS + Hct

6.3.7 Subsystem Test Printer

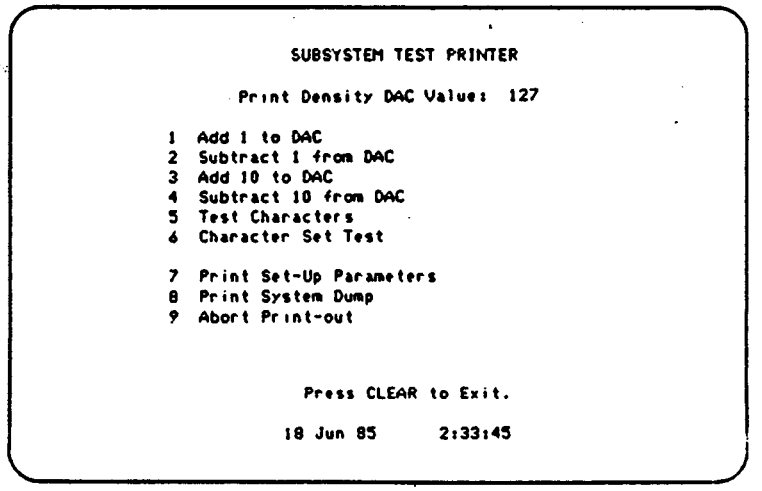
This screen allows:

- Manual adjustment of the print darkness
- Testing of printhead function
- Set-Up Parameter printout
- System Parameter printout
- Termination of a lengthy printout

The NOVA factory-set value of 127 DAC units prints medium print darkness. Increasing the DAC value gives darker print but correspondingly decreases the life of the printhead. Function 5, Test Characters, prints a test pattern useful for print darkness adjustment. Function 6, Character Set Test, prints all possible characters. The Subsystem Test Printer screen, function 7, causes a printout of all set up parameters, modes, and values. The Subsystem Test Printer screen, function 8, causes a System Dump which yields all millivolt, slope, set-up, and other system parameters. Function 9 can be used to stop any printing operation. Note that the printer has a 64-character buffer, so printing may not cease immediately.

Access this screen as follows:

1. From the Service Menu, press 7, accessing the SUBSYSTEM TEST PRINTER Screen.
2. Press 1 - 4 to increase or decrease the print darkness.
3. Press 5 to perform a printout pattern showing all possible print dots, verifying proper function.
4. Press 6 to obtain a printout of all possible characters.
5. Press 7 to obtain a Set-Up parameter printout.



SUBSYSTEM TEST PRINTER

6. Press 8 to obtain a System printout.
7. Press 9 to stop any printing.
8. Press CLEAR to leave this screen.

6.3.8 Subsytem Test Communications

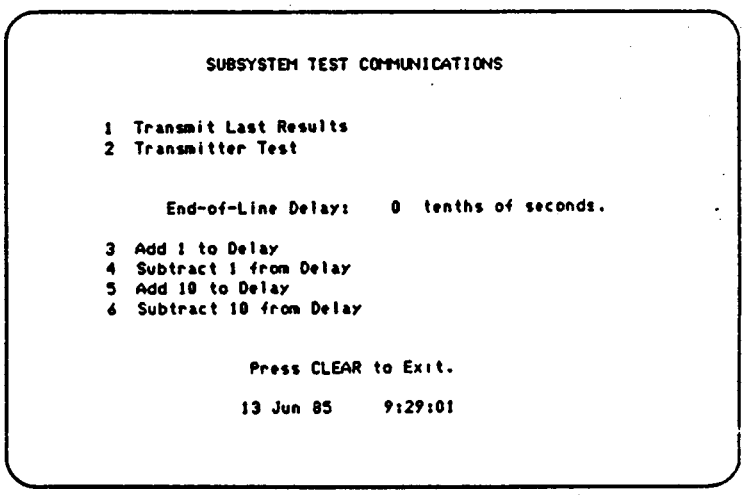
This screen enables

- Manual transfer of test results to external devices
- ASCII character transmission to verify transmitter functioning
- End-of-Line delay adjustments

Test results may be transmitted manually at any time after the analysis has completed and the results have been displayed. If the Manual Transmit mode has been selected in the Set Up menu, this is the only way to transmit results (see Section 2.2.8). The Transmitter Test and End-of-Line Delay Adjust functions are useful for setting up and troubleshooting communications links. Note that once the End-of-Line Delay has been determined on this screen, the value should be programmed into the system as a Set Up parameter (see Section 2.2.7). For more information on the Communications Subsystem, see the Stat Profile Communications Interface Manual.

Access this screen as follows:

1. Press 8, accessing the SUBSYSTEM TEST COMMUNICATIONS screen.
2. Press 1 to transmit results of the last analysis to an external device.
3. Press 2 to perform a Transmitter Test, printing out an ASCII character sequence for transmitter verification.
4. Press 3 - 6 to adjust end-of-line delay to the requirements of the external device.
5. Press CLEAR to leave this screen.



SUBSYSTEM TEST COMMUNICATIONS

7 Reagents and Solutions

This section covers the reagents and solutions required for proper operation and maintenance of the Stat Profile 1 analyzer.

7.1 Reagents and Solutions

Reagents and solutions for the Stat Profile 1 are as follows:

1. Reagent Pack
   - Reference solution
   - Standard A
   - Standard B
   - Standard C
   - Standard D
   - Flush solution
2. Na electrode conditioning solution
3. pH/PCO_2 electrode conditioning solution
4. PO_2 electrolyte solution
5. PCO_2 electrolyte solution
6. NOVA Cleaning Solution
7. Calibration gases
   - Standard A
   - Standard B
8. NOVA Stat Profile Controls
   - Level 1 - Acidosis
   - Level 2 - Normal
   - Level 3 - Alkalosis
9. NOVA Stat Profile Hematocrit Controls
   - Level 1 - Low Normal
   - Level 2 - High Normal

Use ONLY reagents provided by NOVA Biomedical with the Stat Profile 1. These reagents are formulated and manufactured specifically for use with NOVA's electrode technology. Reagents from any other source, though they may appear appropriate for use, can contain agents (preservatives, wetting agents, buffers, etc.) that interfere with Stat Profile 1 electrode performance. Use of such reagents will void the Stat Profile 1 electrode warranty.

NOTE: Refer to the NOVA Stat Profile Control insert for storage requirements for these controls. Store all other NOVA Stat Profile 1 reagents and solutions at 10° to 30° C.

7.2 Reagent Pack

The compositions of the internal standards are given in Table 7.1.

Table 7.1 Internal Standards Concentration, mmol/L

STANDARD	Na^+	K^+	Ca^{++}	pH
A*	--	--	--	7.384
B*	--	--	--	6.840
C	140	4.00	1.00	7.460
D	75	20.00	2.00	--

In addition to the Reagent pack reagents and solutions listed above, the Reagent Pack has a self-contained waste bottle for safe disposal of waste.

7.3 Calibrating Gases

NOVA calibrating gases contain mixed gas for calibrating the PO_2 and PCO_2 electrodes on the Stat Profile 1 analyzer (see Table 7.2)**. Always check the gas composition values on newly replaced gas cylinders against the SET CALIBRATION GASES screen (Section 5.1.8).

Table 7.2 Calibration Gases Composition

Gas Standard A	Specified Value	Accuracy
Carbon Dioxide	5.0 %	± 0.03 %
Oxygen	20.0 %	± 0.03 %
Nitrogen	Balance	---
Gas Standard B	**Specified Value**	**Accuracy**
Carbon Dioxide	10.0 %	± 0.03 %
Nitrogen	Balance	± 0.03 %

*Standards A and B are directly traceable to the National Bureau of Standards Buffers for standardization of pH measurements, cited as follows.

Durst, R. A. Standardization of pH measurements. Standard reference materials. Publication PB248 127. National Bureau of Standards, National Technical Service, 1975

**If for any reason NOVA gases are not used, the alternative gases must be guaranteed accurate to within ± 0.03 % of the specified value. The gases should be of "Clinical Quality". A convenient cylinder size is 52 cm high X 10.5 cm diameter with gas at 2000 PSI.

7.4 NOVA Stat Profile Controls

NOVA Stat Profile Controls provide quality control levels for monitoring sodium, potassium, ionized calcium, pH, PO_2, and PCO_2. These controls are formulated from a buffered bicarbonate solution with a known pH, Na, K, and Ca^{++} level. The solutions are equilibrated with known levels of oxygen and carbon dioxide.

The NOVA Stat Profile Controls are formulated at three clinically significant levels:

Level 1 - Acidosis, with high electrolyte values

Level 2 - Normal, with normal electrolyte values

Level 3 - Alkalosis, with low electrolyte values

The ampules must be stored at room temperature (20° - 25° C) for at least 24 hours before use.

CAUTION: The electrode performance of the Stat Profile 1 may be affected by use of controls other than NOVA Stat Profile Controls and CAP Survey samples.

Analyze the NOVA Stat Profile Controls as follows:

1. Before opening, shake the ampul for about 10 seconds.
2. Snap open the ampul, protecting the fingers with tissue or gloves.
3. Analyze the liquid within ONE MINUTE of opening to prevent contamination with room air, and alteration of stated values.
4. Refer to the Assay Data Sheet enclosed with each package for control values and ranges.

7.5 NOVA Stat Profile Hematocrit Controls

The NOVA Stat Profile Hematocrit Controls are intended for monitoring the performance of the hematocrit channel on the Stat Profile 1. The controls are electrolyte solutions with concentrations of the active ingredients adjusted to give a conductivity signal equivalent to a known hematocrit value in whole blood. The controls are adjusted for the effect of sodium concentration on the conductivity of samples.

The NOVA Stat Profile Hematocrit Controls are formulated at two clinically significant levels:

Level 1 - Normal, Low values

Level 2 - Normal, High values

Ampuls should be stored at room temperature. Avoid freezing or storage above 30°C.

CAUTION:	The electrode performance of the Stat Profile 1 may be affected by use of controls other than NOVA Stat Profile Hematocrit Controls.

Analyze the HEMATOCRIT CONTROLS as follows:

1. Snap open the ampul, protecting the fingers with tissue or gloves.
2. Analyze the control.
3. Refer to the Assay Data Sheet enclosed with each package for the values and ranges of the controls.

8 Theory

This section explains instrument theory.

8.1 Origin of the Potential Measurement

To help understand the ion exchange phenomena that occur at the membrane of the ion selective electrode, consider first the ion exchange taking place at the surface of a simple permeable membrane, such as a dialysis membrane, in a concentration cell between two salt solutions, A and B (Figure 8.1). Because solution B has a smaller concentration of the ions in both solutions, a concentration gradient is set up at the membrane.

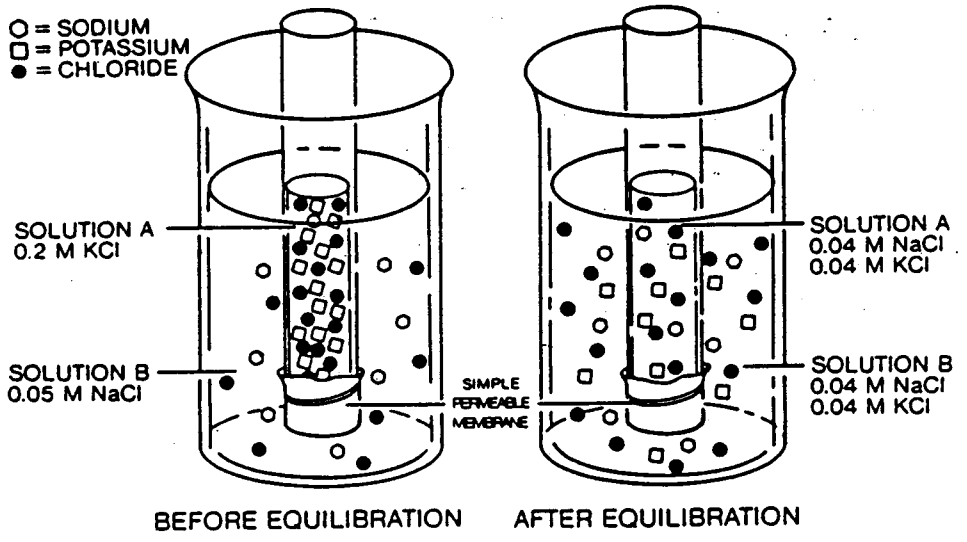


Figure 8.1 Ionic Diffusion

The concentration gradient creates a driving force to send ions in solution from the cell where they are most concentrated across the membrane to the cell where they are less concentrated. This force decreases as the concentration becomes more equal on both sides of the membrane. This equilibration process results in equal salt concentrations on both sides of the membrane and equal rates of migration both ways across the membrane.

At equalibrium, the ratio of the ion concentrations in the two solutions is:

$$\frac{[Cl^-]_o}{[Cl^-]_i} = \frac{[Na^+]_o}{[Na^+]_i} \frac{[K^+]_o}{[K^+]_i} = 1 \qquad \text{Equation 1}$$

where subscripts i and o denote ions on either side of the membrane.

In Figure 8.2, the dialysis membrane is replaced with an ion-selective membrane which can differentiate among ions. For purposes of discussion, a K^+ selective membrane is used. This means the membrane can differentiate potassium ions from all other ions in solution. As the ions in solutions A and B move about, the K^+ ions enter into the ion-selective sites on the membrane surface and leave behind the negatively charged Cl^- ions. The chloride ions

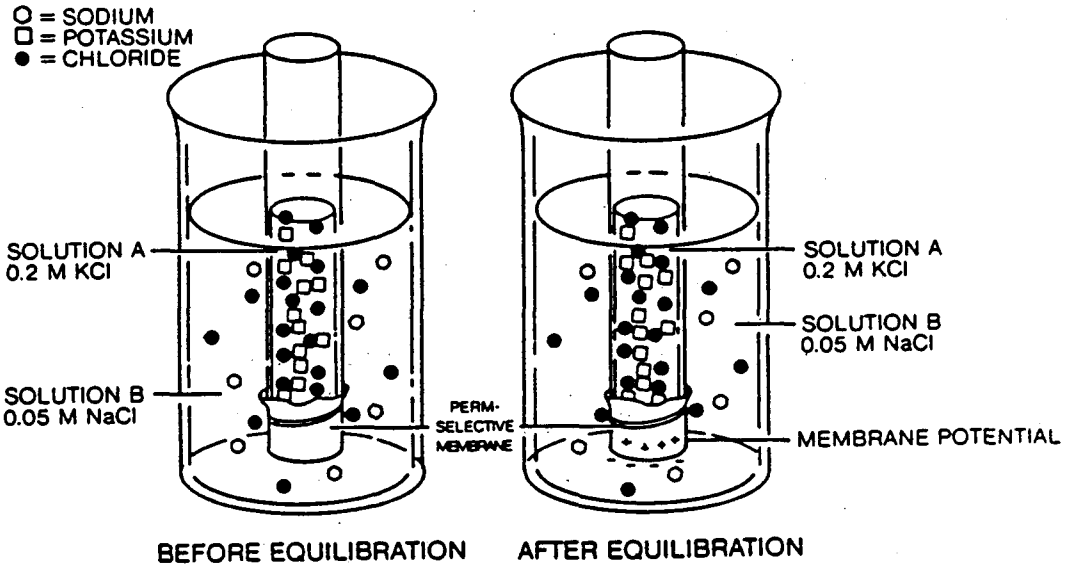


Figure 8.2 Establishment of Membrane Potential

line up adjacent to the membrane and set up a potential which prevents further movement across the membrane surface. At equilibrium, a potential difference, or membrane potential, is established across the membrane. The areas on either side of the membrane can therefore be compared to the two poles of a miniature battery with a voltage equal to the potential difference across the membrane. The membrane potential is dependent on the activities of the potassium ions on either side of the membrane and was described by Nernst:

$$E_m = \frac{RT}{nF} \ln \frac{a_o}{a_i} \qquad \text{Equation 2}$$

where E_m is the membrane potential, a is the activity of the potassium ion, R is the universal gas constant, T is the temperature in degrees Kelvin, F is Faraday's constant and n is the charge of the measured ion: +1 for sodium and potassium, -1 for chloride. (The activity of an electrolyte can be called a measure of its "effective concentration" in solution. It is equal to the concentration multiplied by the ion's activity coefficient, f; that is, a = f x c. The activity coefficient describes an ion's ability to react in solution.)

When the glass tube in Figure 8.2 is filled with a salt solution of constant composition, called the internal filling solution, the electric potential of the membrane depends only on the solution outside the membrane as follows:

$$E_m = E_o + \frac{RT}{nF} \ln a_o \qquad \text{Equation 3}$$

where E_o is a constant that includes a term for a_i the activity of the ion in the IFS.

We can convert from the natural logarithm (ln) in Equation 3 to a base 10 logarithm and an equivalent equation:

$$E_m = E_o + 2.303 \frac{RT}{nF} \log a_o \qquad \text{Equation 4}$$

In order to measure the potential on the ion selective membrane, a complete electrical circuit is needed. A typical ion selective electrode measuring circuit is shown in Figure 8.3. There are two electrodes here: a reference electrode and the ion selective electrode. The potential of the reference electrode is maintained constant; that of the ISE varies, depending on the activity of the ion of interest in the test solution. A voltmeter is used to measure the potential difference between the ion selective electrode and the reference electrode.

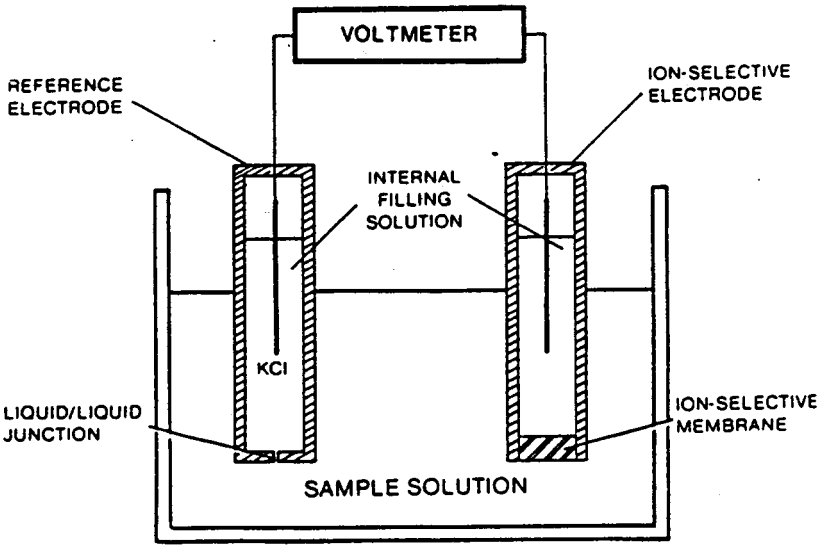


Figure 8.3 Electrode Measuring Circuit

The potential difference of the entire electrode measuring circuit, E_{cell}, is equal to the algebraic sum of the potential from the ion selective electrode, E_m, the reference electrode, E_r, and the junction potential, E_j.

$$E_{cell} = E_m - E_r - E_j \qquad \text{Equation 5}$$

The junction potential is the potential developed at the liquid/liquid junction between the reference electrode and the test solution. The magnitude of the liquid junction potential which arises as a result of the interdiffusion of the ions at the liquid/liquid junction is relatively inconsequential.

By setting $S = 2.303 \frac{RT}{nF}$ and substituting Equation 4 for E_m,

uation 5 can be rewritten:

$$E_{cell} = E_o + S \log a_o - E_r - E_j \qquad \text{Equation 6}$$

S is called the electrode slope. Under ideal conditions at 37° C, it is theoretically equal to approximately 30.8 mV per decade change in activity for a divalent ion and 61.5 mV for a univalent ion. It is the slope of the line obtained by graphing potential, E, vs. the log of the activity,

$$S = \frac{E_{std\ C} - E_{std\ D}}{\log \frac{C}{D}} \qquad \text{Equation 7}$$

where C is the activity of Standard C and D is the activity of Standard D.

When the unknown activity of the ion of interest is measured in a test solution, the potential of the test solution, E_x is compared with that of a standard solution, E_{std}, in which the activity of the ion of interest is known. Most of the terms cancel out as follows:

$$E_x = E_o + S \log a_x - E_r - E_j \qquad \text{Equation 8}$$

minus $$E_{std} = E_o + S \log a_{std} - E_r - E_j \qquad \text{Equation 9}$$

$$\Delta E = S \log a_x - S \log a_{std} = S \log \frac{a_x}{a_{std}} \qquad \text{Equation 10}$$

Thus, the difference in potential between the two solutions, E, is dependent only on the ratio of the activity of the ion of interest in the test solution, a_x, and the activity of the ion of interest in the standard solution, a_{std}.

8.2 Electrode Calibration

8.2.1 Two-Point Calibration

The Stat Profile 1 uses a two-point calibration to measure the electrode slope and verify electrode performance. The Reagent Module and gas cylinders contain the standards which are used for this purpose. Calibration can be initiated manually by pressing CAL, ENTER and is also initiated automatically by the system at intervals of approximately 2 hours.

8.2.2 One-Point Calibration

Electrode drift is the slow variation in electrical potential over time. As expressed in Equation 10, the determination of the activity for an unknown sample is dependent on both the electrode potential generated by the unknown and that generated by the standard. The Stat Profile 1 uses a one-point calibration to monitor and minimize the effect of the electrode drift on the analytical results. In the SINGLE throughput mode, a one-point calibration with Gas A and Standard C is performed with each analysis. In the NORMAL throughput mode, a one-point calibration with Gas A and Standard C is performed at approximately 30 minutes as long as samples are analyzed at a rate of at least one per 15 minutes; if over 15 minutes elapses without a sample analysis, a one-point calibration will automatically be performed with the next analysis. (One-point calibrations can only occur with an analysis.)

An E-Zero or Analysis to Analysis drift error code is displayed when electrode drift is beyond the drift limits.

8.3 Principles of Measurement

8.3.1 Sodium, Potassium, and Ionized Calcium

The electrolyte electrodes require a sensing (ion-selective) membrane, a reference and internal filling solution. Internal filling solution provides a fixed concentration of the ion and the sample provides a second concentration of ion.

A suitable electrode membrane is selectively permeable to a single ion of interest in the sample solution. This selective permeability establishes an electrical potential as the charge associated with the ion leaves its counter-ion behind in solution. The magnitude of this electrical potential is determined by the concentration difference between the two sides of the membrane.

Calculating Sample Concentration

Equation 6 links the voltage of the cell (E_m) to the activity of the ion. Activity is related to concentration (C) through the activity coefficent in the relation $a = f \times C$. The activity coefficient is a function of ionic strength. Thus, Equation 6 can be rewritten in terms of concentration as follows:

$$E_{cell} = E_o + S\,(fC)_o - E_r - E_j \qquad \text{Equation 11}$$

ilarily, Equation 10 is rewritten:

$$\Delta E = E_x - E_{std} = S \log \frac{(fC)_x}{(fC)_{std}} \qquad \text{Equation 12}$$

The ionic strength of whole blood, plasma, and serum tends to remain relatively constant over the physiological range.[1] As a result, the activity coefficients of sodium, potassium, and calcium can be assumed to be constant. The internal standards are formulated to reflect the same ionic strength as that of whole blood. Therefore, a given ion's activity coefficient can be assumed to be equal in the standard and sample. The activity coefficient terms in Equation 12 cancel out resulting in:

$$\Delta E = E_x - E_{std} = S \log \frac{C_x}{C_{std}} \qquad \text{Equation 13}$$

By holding C_{std} in Equation 13 constant, E is dependent on only one variable, C_x, the concentration of the ion of interest in the sample. Equation 14 can be rearranged to isolate this variable:

$$C_x = (C_{std})\ 10^{(\Delta E/S)} \qquad \text{Equation 14}$$

The Stat Profile 1 microcomputer uses Equation 14 to calculate the concentration of sodium, potassium, and calcium ions in the sample.

3.2 pH Electrode

Principle of pH Measurement

pH is measured using a hydrogen ion selective glass membrane. One side of the glass is in contact with a solution of constant pH. The other side is in contact with solution of unknown pH. A change in potential develops which is proportional to the pH difference of these solutions. This change in potential is measured against a reference electrode of constant potential. The magnitude of the potential difference is a measure, then, of the pH of the unknown solution.

Definition of pH

The pH is defined as the negative logarithm of the hydrogen ion activity.

$$pH = -\log_{10} a_{H+} \qquad \text{Equation 15}$$

Thus when negative pH is substituted for the logarithm of the activity in Equation 10, the equation becomes:

$$E = E_x - E_{std} = -SpH_x - (-SpH_{std}) \qquad \text{Equation 16}$$

Equation 16 can be rearranged so that pH, the pH of the unknown sample, can be calculated by the NOVA Stat Profile microcomputer using two calibrating solutions of known pH:

$$pH_x = pH_{std\ A} + \frac{E_x - E_{std\ A}}{Slope} \qquad \text{Equation 17}$$

where:

$$Slope = \frac{E_{std\ A} - E_{std\ B}}{pH_{std\ A} - pH_{std\ B}}$$

8.3.3 Partial Pressure of Carbon Dioxide (PCO_2)

Definition of PCO_2

The partial pressure (tension) of carbon dioxide in solution is defined as the partial pressure of carbon dioxide in the gas phase in equilibrium with the blood.

Principle of PCO_2 Measurement

PCO_2 is measured with a modified pH electrode. Carbon dioxide in the unknown solution makes contact with a gas permeable silicone membrane mounted on a combination measuring/reference electrode. CO_2 diffuses across the membrane into a thin layer of electrolyte solution in response to partial pressure difference. This solution then becomes equilibrated with the external gas pressure. CO_2 in the solution becomes hydrated producing carbonic acid which results in a change in hydrogen ion activity.

$$CO_2 + H_2O \rightleftharpoons H_2CO_3 \rightleftharpoons H^+ + HCO_3^- \qquad \text{Equation 18}$$

The electrolyte solution behind the membrane is in contact with a glass hydrogen ion selective electrode. The change in hydrogen ion activity in the electrolyte solution produces a potential which is measured against the internal filling solution. This change in potential is measured against the constant potential of the reference electrode half cell and is exponentially related to the PCO_2 of the unknown sample.

8.3.4 Partial Pressure of Oxygen (PO_2)

Definition of PO_2

The partial pressure (tension) of oxygen in solution is defined as the partial pressure of oxygen in the gas phase in equilibrium with the blood. PO_2 provides an indication of the availability of oxygen in inspired air.

Principle of PO_2 Measurement

PO_2 is measured amperometrically by the creation of a current at the electrode surface. As oxygen diffuses through a polypropylene membrane, the oxygen molecules are reduced at the cathode, consuming 4 electrons for every molecule of oxygen reduced. This flow of electrons is then measured by the electrode and is directly proportional to the partial pressure of oxygen.

3.5 Hematocrit

Hematocrit, defined as the percentage of red blood cells to total blood volume, is measured by using the known electrical resistance of red blood cells in blood samples. The STAT Profile 1 measures the hematocrit with an impedance electrode, and, after accounting for sodium's electrical effect, is calculated as follows:

$$Hct\ \% = 1 - \frac{1}{R_{Corr}} \times 100 \qquad \text{Equation 19}$$

where R_{Corr} equals the corrected resistance factor obtained from a particular sample corrected for the concentration of the sodium. The resistance correction factor is determined as follows:

$$R_{Corr} = R_{Samp} \times \frac{[\ Na^{+}\ ]}{140.0} \qquad \text{Equation 20}$$

where R_{Samp} is equal to the actual resistance of the sample measured at the air detector.

8.4 Calculated Values

The STAT Profile microcomputer uses the measured results to calculate other clinically valuable parameters. This section outlines the equations used to derive these calculated values.

8.4.1 Temperature Correction for Measured Values*

The Stat Profile Analyzer allows you to enter the patient temperature when this differs from 37° C, as for example in patients having surgery under hypothermia. The pH, PCO_2, and PO_2 sample values, at the patient's actual temperature are then calculated as follows:

- $pH_{(corrected)} = pH + (- 0.0147 + 0.0065\ (7.400 - pH))(T - 37)$

Equation 21

- $PCO_{2(corrected)} = PCO_2 \times e\ (0.04375\ (T - 37))$

Equation 22

- $PO_{2(corrected)} =$

$$PO_2 \times e\ [(2.303)\ (T - 37) \times \frac{((5.49 \times 10^{-11})\ Y + 0.071)}{((9.72 \times 10^{-9})\ Y + 2.30)}]$$

Equation 23

where $Y = e\ (3.88 \times \ln(PO_2))$

8.4.2 Calculated Parameters

Ionized Calcium "Normalized" to pH 7.4

The activity and concentration of ionized calcium in whole blood, plasma, and serum is pH dependant. In vitro, a pH increase of 0.1 unit decreases the ionized calcium level by 4 to 5 % (conversely, a pH decrease has an equal but opposite effect). On standing the pH of plasma and serum samples rises due to the loss of CO_2. The samples of choice for ionized calcium determination are anaerobically collected whole blood, plasma, or serum.

*The equations are from the NCCLS standards[2].

an anaerobic sample is not available, by measuring the actual pH of the ple at which the ionized calcium concentration was measured normalized ion- ed calcium can be calculated. The normalized ionized calcium represents what the ionized calcium concentration would have been if the initial pH was 7.40 (the midpoint of the pH reference range). The equation used for this calculation is:

$$\log [Ca^{++}]\ 7.4 = \log [Ca^{++}]X - 0.24\ (7.4 - X) \qquad \text{Equation 24}$$

where

X = measured pH of the sample

$[Ca^{++}]X$ = ionized calcium concentration in the sample at the measured pH.

$[Ca^{++}]7.4$ = normalized concentration of ionized calcium at pH 7.40.

The equation assumes a normal concentration of total protein and may be used for measured values between pH 7.2 and 7.6. Between pH 6.9 and 7.2 and between pH 7.6 and 8.0, modified forms of the equation are used. Normalized ionized calcium values for samples with pH outside the range pH 6.9 to pH 8.0 are not displayed.

Calculated Bicarbonate Concentration (HCO_3^-)*

carbonate Concentration is calculated using the Henderson-Hasselbalch equa- ion:

$$pH = pK + \log \frac{[HCO_3^-]}{\alpha PCO_2} \qquad \text{Equation 25}$$

where pH and PCO_2 are measured.

pK = 6.091

α = 0.0307 = solubility coefficient of CO_2 in plasma at 37° C

Rearranging Equation 25 gives

$$\text{Log}_{10}[HCO_3^-] = pH + \log_{10} PCO_2 - 7.604 \qquad \text{Equation 26}$$

Total Carbon Dioxide Content (TCO_2)*

TCO_2 includes both dissolved carbon dioxide and HCO_3^- and is calculated as follows:

$$TCO_2 = [HCO_3^-] + (\alpha \times PCO_2) \qquad \text{Equation 27}$$

here PCO_2 is measured and $[HCO_3^-]$ is calculated from Equation 26.

*The equations are from the NCCLS standards[2].

Hemoglobin

Calculated hemoglobin is based on the measured hematocrit as follows:

$$\text{Hemoglobin g/dl} = \text{Measured Hematocrit \%} \div 3.0 \qquad \text{Equation 28}$$

NOTE: The mmol/L (Hb/4) unit for hemoglobin is an S. I. unit. The calculation is based on a hemoglobin monomer with a relative molecular mass of 16,114.

Base Excess of Blood (BE-B - sometimes called In Vitro Base Excess)*

Base excess of blood is defined as the number of millimoles of strong acid or base needed to titrate one liter of blood to pH 7.40 at 37° C while the PCO_2 is held constant at 40 mm Hg. Base excess of blood is calculated as follows:

$$BE\text{-}B = (1 - .014[Hb])([HCO_3^-] - 24 + (1.43[Hb] + 7.7)(pH - 7.4)) \qquad \text{Equation 29}$$

Standard Bicarbonate Concentration (SBC)

The Standard Bicarbonate is defined as the bicarbonate concentration of the plasma of whole blood equilibrated to a PCO_2 of 40 mm Hg at a temperature of 37 ° C with the hemoglobin fully saturated with oxygen. Standard bicarbonate is calculated as follows:

$$SBC = 24.5 + 0.9Z + Z(Z - 8)(.004 + .00025[Hb]) \qquad \text{Equation 30}$$

where $Z = [BE\text{-}B] - .19[Hb]((100 - [O_2Sat])/100)$

[Hb] = The hemoglobin value which is measured, manually entered, or is is the 14.3 g/100 ml default value

Base Excess Extracellular Fluid (BE-ECF)*

The Base Excess Extracellular fluid is a corrected form of the Base Excess Blood in which allowance has been made for the fact that blood is only approximately 37% of the extracellular fluid volume. Base excess is calculated as follows:

$$BE\text{-}ECF = [HCO_3^-] - 25 + 16.2(pH - 7.40) \qquad \text{Equation 31}$$

*The equations are from the NCCLS standards[2].

Oxygen Saturation (O_2Sat)

Oxygen saturation is defined as the amount of oxyhemoglobin in blood expressed as a fraction of the total amount of hemoglobin able to bind oxygen. It is calculated as follows:

$$\text{Oxygen Saturation} = \frac{(PO_2')^3 + 150\,(PO_2')}{(PO_2)^3' + 150\,(PO_2') + 23400} \times 100 \qquad \text{Equation 32}$$

where

$$PO_2' = PO_2 \times e\,[2.3026 \times (0.48\,(pH - 7.4) - 0.0013\,([HCO_3^-] - 25))$$

NOTE: The equation for calculating oxygen saturation assumes a normal shape and position of the patient's oxygen dissociation curve.

Oxygen Content (O_2Ct)

Oxygen content is defined as the total amount of oxygen contained in a given volume of whole blood, including dissolved oxygen and oxygen bound to hemoglobin and is usually expressed as milliliters of oxygen per 100 milliliters of blood. It is calculated from the oxygen saturation and the hemoglobin concentration. Four moles of oxygen (22,393 ml/mol at standard temperature and pressure) can combine with 1 mol of hemoglobin (64,458 g/mol) so that oxygen capacity is equal to

$$\frac{4 \times 22{,}393}{64{,}458} = 1.39 \text{ ml of } O_2 \text{ per gram of Hb} \qquad \text{Equation 33}$$

$$\text{therefore} \quad O_2Ct = 1.39[Hb] \times \frac{O_2 sat}{100} \qquad \text{Equation 34}$$

On the Stat Profile 1, Hb can be manually entered, calculated from the measured hematocrit, or occur as a default value of 14.3 (see Section 2.2.7).

References:

1. M.S. Mohan and R.G. Bates: "Blood pH, Gases and Electrolytes." NBS Special Publication 450, U.S Government Printing Office, 1977, p.293

2. Tentative Standard for Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis. National Committee for Clinical Laboratory Standards. NCCLS publication: vol. 2 no. 10. 1982.

9 INSTALLATION

This section covers the installation requirements and assembly procedures.

NOTE: The Stat Profile 1 warranty requires the initial installation to be performed by a NOVA service representative.

To reinstall an instrument also follow these guidelines.

9.1 Requirements

Working Area Requirements

Do not install the instrument above any instrument, apparatus, etc. that could be damaged by fluid from the the spill tubing located by the gas ports cut-out. Keep the working area near the system free from dirt, corrosive fumes, vibration, and excessive temperature changes. Ambient operating temperature is 16° to 32° C (61° F to 90° F).

Electrical Requirements

A grounded, three-wire receptacle within 5 feet of the system is required for operation. The U.S. models require a 120 Volt a. c. line at 50 - 60 Hz frequency. The instruments can be converted to operate at different voltage ratings.

Fuse requirements: 6 Amp SLO-BLO, 4 Amp SLO-BLO at 120 Volt AC line. For other fuse requirements, see Section 5.4.21.

Gas Calibrating Requirements

The instrument calibration gas supply compositions are given in Section 7.2. For use of gas from suppliers other than NOVA refer to Section 7.2 for correct concentrations and tolerances. Each tank requires a gas regulator gauge pressure of approximately 5 $\pm$ 1 PSIG. Regulators for gas cylinders are included with the accessory pack.

9.2 Installation Procedure

For maximum efficiency follow this installation procedure.

1. Connnect the gas hoses to the instrument per Section 5.4.20.
2. Install the Septum Assembly per Section 5.4.13.
3. Install the W/R Harness per Section 5.4.8.
4. Install the Septum Harness per Section 5.4.11.
5. Install the Reagent Harness per Section 5.4.10.
6. Install the Reagent Pack per Section 5.4.12.
7. Connect the power cord to the instrument at the back of the instrument then plug the instrument into the line voltage.

8. Perform a barometer check as follows:

   a. Press MENU, 1, 3, accessing the SET BAROMETRIC PRESSURE screen.
   b. Note the barometric pressure reading. The barometric pressure reading should agree within ± 2 mm mercury with a reliable reference value such as a lab barometer or an altitude-corrected weather bureau reading. If the values are not in agreement, see Section 3.2.5 to calibrate the barometer.
   c. Press CLEAR twice to return to the MAIN MENU.

9. Check the Sampler Probe position as follows per Section 6.3.1.7, Probe Placement Test.
10. Turn on both gas cylinders, opening the regulators completely, and verify that the gas delivery pressure is at approximately 5 PSI ± 1 and that the volume is at about 2000 PSI. If the gas pressure is incorrect, refer to Section 5.4.20 to adjust the regulators.
11. Assemble and attach the Sample Preheater-Flow Cell-Reference electrode unit to the Electrode Rack Assembly per Section 5.4.15. Do not install the electrodes into the Flow Cell yet.
12. Attach the S Line to the bottom of the Sample Preheater by sliding the tubing over the Sample Preheater connector, then sliding the crimp lock over the connection.
13. Perform Sections 5.3.5, 5.3.6, and 5.3.7, preconditioning and installing the electrodes in the Flow Cell.
14. Press CLEAR, CLEAR, 2, 7, ENTER to initiate a fluid prime. Wait until the cycle is complete, then press 2, 7, ENTER for a final prime.
15. Press MENU, 2, 6, ENTER to initiate a gas prime. Wait until the cycle is complete.
16. Remove the 2 humidifier caps and fill each humidifier to the line with deionized water.

    NOTE: Do not overfill the humidifiers.

17. Follow the Program Initialization procedure (Section 2).

10 INSTRUMENT SPECIFICATIONS, ORDERING INFORMATION AND WARRANTY

This section covers Instrument Specifications, Ordering Information, and Warranty.

10.1 Instrument Specifications*

Measurement Range	Hct	2% - 70%
	Na	80 - 200 mM
	K	1.0 - 20.0 mM
	Ca^{++}	0.1 - 4.9 mM
	pH	6.50 - 8.00
	PCO_2	3.0 - 200 mm Hg
	PO_2	0 - 800 mm Hg
Acceptable Samples	Whole Blood Plasma (for Na/K/Ca^{++} only) Serum (for Na/K/Ca^{++} only)	
Measuring Technology	Ion Selective Electrodes (Na, K, Ca^{++}, pH, PCO_2) Amperometry (PO_2) Conductivity (Hematocrit)	
Analysis Rate	Single Throughput - 20 samples/hour Normal Throughput - 38 samples/hour.	
Sample Volume	250 microliters whole blood, plasma, serum	
Barometer	450 - 800 $\pm$ 2 mm Hg	
Reagents	A single Reagent Pack contains all fluids for 300 samples (2100 tests)	

Calibration Gases

Two (2) Gas cylinders are "E" size and contain gases as follows:

Gas Standard A	Specified Value	Accuracy
Carbon Dioxide	5.0 %	$\pm$ 0.03 %
Oxygen	20.0 %	$\pm$ 0.03 %
Nitrogen	Balance	---

Gas Standard B	Specified Value	Accuracy
Carbon Dioxide	10.0 %	$\pm$ 0.03 %
Nitrogen	Balance	---

Slope Limits

pH	9.0 - 10.5
PO_2	-2.0 - -7.0
PCO_2	7.9 - 11.3
Hct	45.0 - 98.0
Na	9.0 - 10.7
K	8.8 - 10.9
Ca^{++}	8.9 - 11.6

Stat Profile 1 Typical Day-To-Day Precision
(NOVA Stat Profile Controls)

Constituent	Statistic	Level 1	Level 2	Level 3
pH	Mean	7.154	7.356	7.555
	S. D.	0.004	0.005	0.005
PCO_2 (mm Hg)	Mean	71.8	46.7	23.3
	S. D.	1.52	0.97	0.50
	C. V. %	2.1	2.1	2.1
PO_2 (mm Hg)	Mean	55.8	97.9	138.6
	S. D.	1.69	2.75	3.29
	C. V. %	3.0	2.8	2.4
Hematocrit (%)	Mean	28.0	56.4	
	S. D.	0.33	0.69	
	C. V. %	1.2	1.2	
Sodium (mmol/L)	Mean	156.9	135.9	117.2
	S. D.	0.55	0.34	0.56
	C. V. %	0.4	0.3	0.5
Potassium (mmol/L)	Mean	5.78	3.90	1.87
	S. D.	0.072	0.043	0.032
	C. V. %	1.2	1.1	1.7
Ionized Calcium (mmol/L)	Mean	1.54	1.05	0.53
	S. D.	0.023	0.009	0.011
	C. V. %	1.5	0.9	2.1

N = 19 Days

Electrical Compliance	To meet UL and CSA Standards
Temperature Thermostatting	37°C ± 0.1°C
Power	100/120/200/220/240 V ± 10%, 50/60 Hz
FDA Labeling	For In Vitro diagnostic use
Warranty	One year on all parts and workmanship except electrodes** (6 months) and tubing (30 days)

*Specifications are subject to change.
**Special warranty applies to the ionized calcium electrode.

10.2 Ordering Information

Supplies and parts for the Stat Profile 1 are available from NOVA Biomedical.

DESCRIPTION	ITEM #
Stat Profile System	06034
Gas Calibration Kit	06588
Calibration Gas A	06586
Calibration Gas B	06587
Cylinder Stand	06546
Cylinder Hose	06548
Regulator	06545
Hose Clamps	06549
Washer Removal Tool	07157
Wrench	06547
Instruction Manual	07017
Maintenance Log	06530
Quick Reference Sheet	06654
Flow Cell	06017
Calcium Electrode	06007
PCO_2 Electrode	07541
pH Electrode	06013
PO_2 Electrode	06015
Potassium Electrode	06009
Reference Electrode	06025
Sodium Electrode	06011
PCO_2 Membrane Kit	07543
PCO_2 Wick Insertion Tool	07542
PO_2 Membrane Kit	06569
PO_2 Membrane Tool	06532
Washer Replacement Kit	07159
Reagent Harness	06516
Septum Harness	06517
W/R Harness (2/Box)	07272
W/R Tubing Segments	07501
Interconnect Tubing	07161
Reagent Pack	05415
Electrode Cleaning Solution	06979
External Control Level 1, Acidosis	06550
External Control Level 2, Normal	06551
External Control Level 3, Alkalosis	06552
External Control Multipack	06839
Hematocrit Level 1, Low Normal	07494
Hematocrit Level 2, High Normal	07495
PCO_2 Electrolyte Solution	06553
PO_2 Electrolyte Solution	06554
pH/PCO_2 Cond'ing Solution	06857
Na Conditioning Solution	06856
Capillary Adapters	06529

DESCRIPTION	ITEM #
Sample Preheater(Flow Cell holder)	06525
Line Power Cord	01498
Probe Adjustment Tool	07190
Filters (10/box)	07158
Printer Paper (10 Rolls)	00026
Sampler Probe-S Line	06523
Septum Assembly	06558
Shorting Strap 6 Parameter	06528
Sampler Probe Cleaning Kit	02702

10.3 Warranty

Subject to the exclusions and upon the conditions specified below, NOVA Biomedical or the authorized NOVA Biomedical distributor warrants that he will correct free of all charges including labor, either by repair, or at his election, by replacement, any part of an instrument which fails within one (1) year after delivery to the customer because of defective material or workmanship. This warranty does not include normal wear from use and excludes: (A) Service or parts required for repair to damage caused by accident, neglect, misuse, altering the NOVA equipment, unfavorable environmental conditions, electric current fluctuations, work performed by any party other than an authorized NOVA representative or any force of nature; (B) Work which, in the sole and exclusive opinion of NOVA, is impractical to perform because of location, alterations in the NOVA equipment or connection of the NOVA equipment to any other device; (C) Specification changes; (D) Service required due to use of expendables and/or reagents not approved by NOVA; (E) Service required because of problems, which, in the sole and exclusive opinion of NOVA, have been caused by any unauthorized third party; or (F) Instrument refurbishing for cosmetic purposes. All parts replaced under the original warranty will be warranted only until the end of the original instrument warranty. All requests for warranty replacement must be received by NOVA or their authorized distributor within thirty (30) days after the component failure. NOVA Biomedical reserves the right to change, alter, modify or improve any of its instruments without any obligation to make corresponding changes to any instrument previously sold or shipped. The exceptions to the above are the following:

1. The ionized calcium electrode is warranted as stated on the insert shipped with the electrode.

2. The sodium, potassium, pH, PCO_2, and PO_2 electrodes are warranted for six (6) months from the date of use provided they are stored at room temperature and placed into service prior to the date stated on the electrode(s).

3. Consumable items, including the Reagent Pack, Calibration Gases, replaceable membranes, tubing and tubing harnesses, Electrolyte Solutions, external standards, and Septum Assemblies are warranted to be free of defects for the replacement time period recommended in Table 5.1 or for 30 days -- whichever comes first -- from the time of use. All defects must be promptly reported to NOVA Biomedical in writing and the items must have been placed into service before the date stated on the package.

4. Freight is paid by customer.

THE FOREGOING OBLIGATIONS ARE IN LIEU OF ALL OTHER OBLIGATIONS AND LIABILITIES INCLUDING NEGLIGENCE AND ALL WARRANTIES, OF MERCHANTABILITY OR OTHERWISE, EXPRESSED OR IMPLIED IN FACT BY LAW AND STATE OUR ENTIRE AND EXCLUSIVE LIABILITY AND BUYER'S EXCLUSIVE REMEDY FOR ANY CLAIM OF DAMAGES IN CONNECTION WITH THE SALE OR FURNISHING OF GOODS OR PARTS, THEIR DESIGN, SUITABILITY FOR USE, INSTALLATION OR OPERATION. NOVA BIOMEDICAL WILL IN NO EVENT BE LIABLE FOR ANY SPECIAL OR CONSEQUENTIAL DAMAGES WHATSOEVER, AND OUR OUR LIABILITY UNDER NO CIRCUMSTANCES WILL EXCEED THE CONTRACT PRICE FOR THE GOODS FOR WHICH THE LIABILITY IS CLAIMED.

IN ORDER FOR THE WARRANTY TO BE EFFECTIVE, THE WARRANTY CARD MUST BE SENT TO NOVA BIOMEDICAL, 200 PROSPECT ST., WALTHAM, MASSACHUSETTS, USA.

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5.4.8 Old-Style PCO_2 Electrode Conditioning, Membraning, and Replacement

This procedure is for the old-style PCO_2 electrode (PN 06019), identifiable by the fill hole located midway from the sleeve front. Use this alternative procedure whenever Section 5.4.8 is referenced in the text. The PCO_2 Membrane Kit part number is PN 06568.

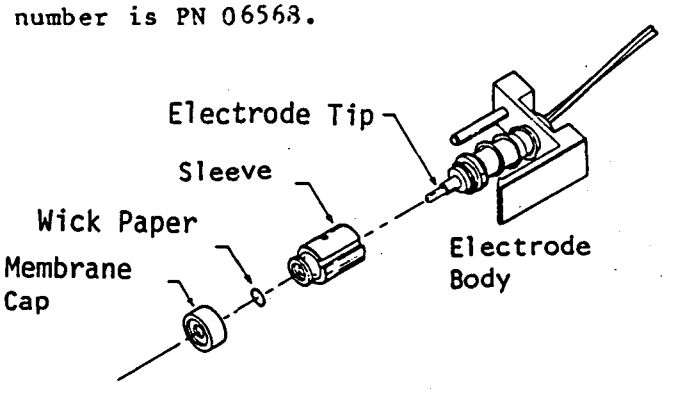

Figure 1 PCO_2 Electrode Assembly

1. From the Ready For Analysis screen, press MENU, 3, 1, 9, 8, 6 to manually prime gas and displace fluid from the flow cell.
2. After 10 seconds, press 8, 0, 9 to stop the gas prime.
3. Press 3 to change the PO_2 gain to Low. (Do this to delay automatic flush or calibration cycles for maintenance -- movement of any System Test function will result in delay of the cycles, but the PO_2 gain is the most convenient.)
4. Open the analyzer compartment door.
5. Unplug the electrode cable from the electrode rack assembly.
6. Unclip the PCO_2 electrode and remove from the flow cell.
7. Remove the PCO_2 washer using the washer removal tool (hook the washer with the hook end of the tool) and, with a lintless tissue or swab, dry the electrode chamber and washer throroughly. If bubble hang up at the electrode tip was a problem, or if other problems suggest a bad washer, replace the washer.
8. Position the thick, small hole washer on the broad end of the washer removal tool (see Figure 2) and, aligning the groove on the washer removal tool with the flow cell alignment pin, insert it into the flow cell, seating it against the back wall of the chamber.

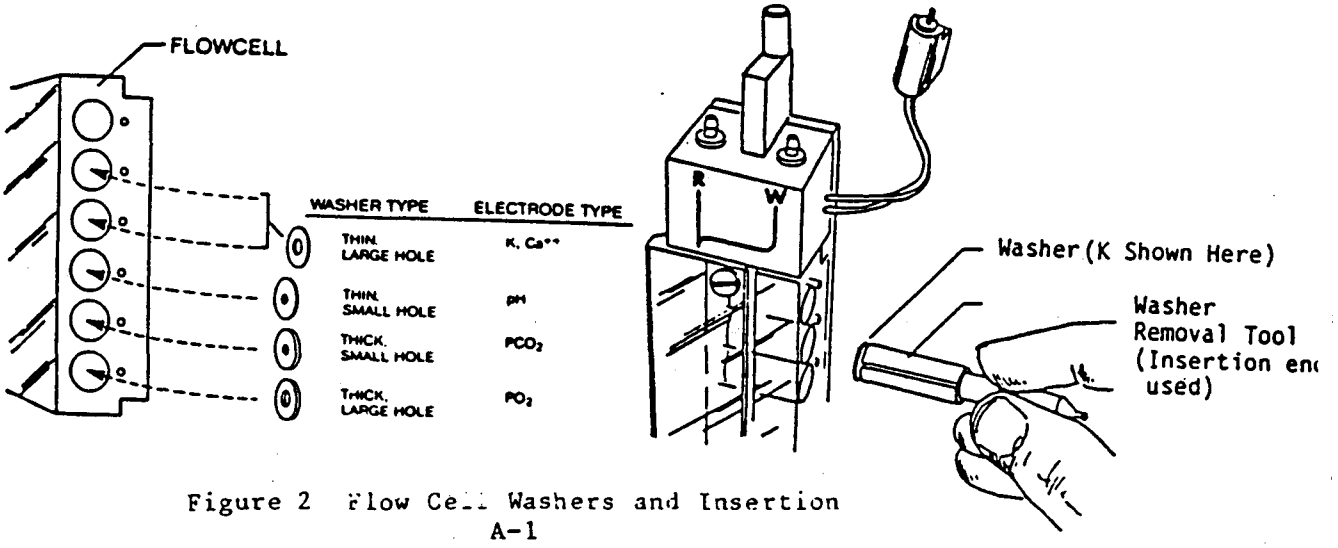

Figure 2 Flow Cell Washers and Insertion

9. Close the analyzer compartment door.
10. Remove the PCO_2 sleeve/cap unit from the top of the electrode (see Figure 1) by pulling straight off.
11. Remove and discard the old membrane cap and wick paper from the sleeve.
12. If the electrode is new, or if you are performing a troubleshooting procedure, condition the electrode as follows. Otherwise, continue with Step 13.

    a. Fill a 2 ml sample cup 1/2 full with pH/PCO_2 Conditioning Solution.
    b. Place the measuring end of the electrode into the sample cup so that the tip of the electrode is immersed in the pH/PCO_2 Conditioning Solution.
    c. Condition for 15 minutes.
    d. Remove the electrode from the cup and rinse with deionized water.
    e. Dry the electrode tip with a lintless tissue.

13. Place a piece of wick paper into the recess on the sleeve and put a drop of electrolyte solution on the paper (Figure 3). The electrolyte solution will cause the paper to stick to the sleeve.

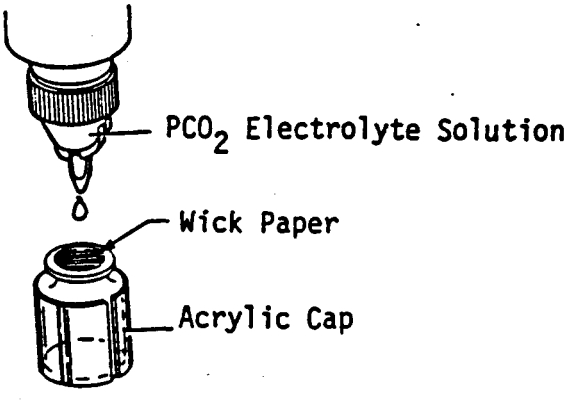

Figure 3 Sleeve Preparation

NOTE: When assembling the electrode, touch the membrane cap on the edges only; avoid contact with the measuring surface of the membrane cap.

14. Install the membrane cap on the sleeve cap by hooking one edge of the cap onto the rim of the sleeve and working the cap over the sleeve rim (Figure 4). Be careful not to disturb the wick paper or touch the external membrane cap surface during this procedure.

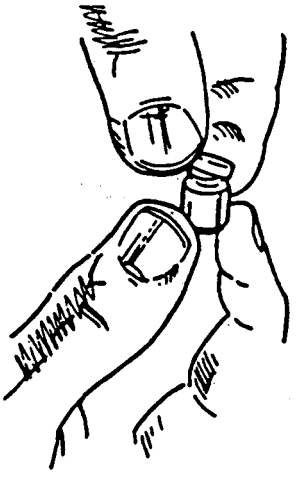

Figure 4 Sleeve-Membrane Cap Installation

15. Fill the sleeve/cap unit to the vent hole with PCO_2 Electrolyte Solution.
16. Tilt the membraned cap at a 45° angle and, with the fill hole up (to avoid leaking solution out the fill hole), insert the electrode into the cap, pressing down firmly to ensure a good seal (Figure 5).

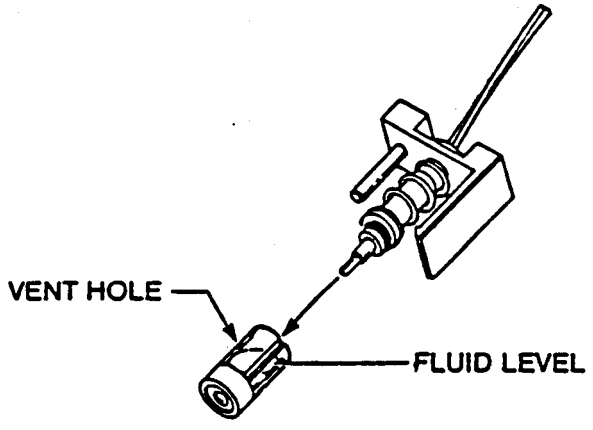

Figure 5 Electrode-Sleeve/Cap Insertion

17. Degas the electrode as follows:

    a. Hold the electrode with the cap downward. Cover the vent hole, and with a wrist-snapping motion, shake the electrode down to move air bubbles to the back of the electrode.
    b. With the electrode tip still downward, observe the tip for bubbles. If bubbles are present, tap the electrode with a finger to loosen the bubbles and again shake the electrode down. Repeat if necessary.

18. Dry the outside of the electrode body with a lintless tissue. Do not touch the surface of the membrane.
19. Open the analyzer compartment door.
20. Insert the electrode into the flow cell by aligning the groove on the sleeve so that it is aligned with the flow cell chamber alignment pin (Figure 6). Next, insert the electrode guide pin and electrode body into the flow cell, clipping the electrode into place. Plug the cable into the electrode rack assembly. Close the analyzer compartment door.

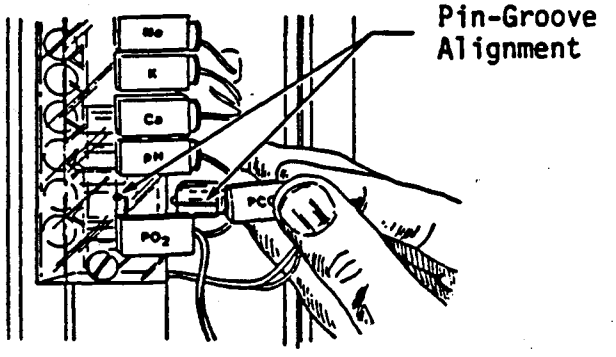

Figure 6 PCO_2 Electrode-Flow Cell Alignment

21. Wait 15 minutes for the electrode to come to temperature.
22. Press CLEAR, CLEAR, CLEAR to return to the Ready (Not Ready) for Analysis screen.
23. Condition with whole blood as follows:

    NOTE: All electrodes must be in the flow cell during a Flow Cell Conditioning cycle.

    a. Fill a 2 ml sample cup 1/2 full of whole blood.
    b. From the Ready For Analysis screen, press MENU, 2, 5 and present the blood to the probe.
    c. Press ANALYZE to aspirate the blood. Withdraw the cup when the probe retracts.

24. After completion of the conditioning cycle, press MENU, 2, 1, ENTER, initiating a gas calibration to verify electrode performance. If the electrode does not calibrate due to slope errors, remove air bubbles as follows:

    a. Open the analyzer compartment door, remove the electrode, unplug the cable, and degas per Step 17. Do not add more Electrolyte solution.
    b. Reinsert the electrode into the flow cell per Step 20, and close the analyzer compartment door.
    c. Press MENU, 2, 1, ENTER, again initiating a gas calibration to verify electrode performance.

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NOVA biomedical

STAT PROFILE

WARRANTY REGISTRATION CARD

CUSTOMER COPY
(to be retained by customer)

Analyzer Serial No. _____

Unit sold by: Delivery Date _____

Distributor _____

Address _____

City _____ State _____ Zip _____

THIS IS YOUR WARRANTY
TO PROTECT YOURSELF - MAIL IN FACTORY COPY
RETAIN THIS COPY FOR YOUR FILES

Cut and detach before mailing

NOVA biomedical

WARRANTY REGISTRATION CARD STAT PROFILE

FACTORY COPY
(to be sent to Waltham, Massachusetts)

Analyzer Serial No. _____

Delivery Date _____

Operator Name _____

Laboratory _____

Company or Institution _____

Address _____ Telephone No. ( ) _____

City _____ State _____ Zip _____

Distributor purchased from: _____

City _____ State _____ Zip _____

Installed by: _____
Service Representative Date

_____
Customer Signature

NOVA BIOMEDICAL
CUSTOMER'S WARRANTY
NOVA STAT PROFILE ANALYZER

[redacted]ANTY

[redacted] to the exclusions and upon the conditions specified below, NOVA [redacted]dical or the authorized NOVA Biomedical distributor warrants that he will correct free of all charges including labor, either by repair, or at his election, by replacement, any part of an instrument which fails within one (1) year after delivery to the customer because of defective material or workmanship. This warranty does not include normal wear from use and excludes: (A) Service or parts required for repair to damage caused by accident, neglect, misuse, altering the NOVA equipment, unfavorable environmental conditions, electric current fluctuations, work performed by any party other than an authorized NOVA representative or any force of nature; (B) Work which, in the sole and exclusive opinion of NOVA, is impractical to perform because of location, alterations in the NOVA equipment or connection of the NOVA equipment to any other device; (C) Specification changes; (D) Service required due to use of expendables and/or reagents not approved by NOVA; (E) Service required because of problems, which, in the sole and exclusive opinion of NOVA, have been caused by any unauthorized third party; or (F) Instrument refurbishing for cosmetic purposes. **All parts replaced under the original warranty will be warranted only until the end of the original instrument warranty. All requests for warranty replacement must be received by NOVA or their authorized distributor within thirty (30) days after the component failure.** NOVA Biomedical reserves the right to change, alter, modify or improve any of its instruments without any obligation to make corresponding changes to any instrument previously sold or shipped. The exceptions to the above are the following:

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4. Freight is paid by customer.

THE FOREGOING OBLIGATIONS ARE IN LIEU OF ALL OTHER OBLIGATIONS AND LIABILITIES INCLUDING NEGLIGENCE AND ALL WARRANTIES, OF MERCHANTABILITY OR OTHERWISE, EXPRESSED OR IMPLIED IN FACT BY LAW AND STATE OUR ENTIRE AND EXCLUSIVE LIABILITY AND BUYER'S EXCLUSIVE REMEDY FOR ANY CLAIM OF DAMAGES IN CONNECTION WITH THE SALE OR FURNISHING OF GOODS OR PARTS, THEIR DESIGN, SUITABILITY FOR USE, INSTALLATION OR OPERATION. NOVA BIOMEDICAL WILL IN NO EVENT BE LIABLE FOR ANY SPECIAL OR CONSEQUENTIAL DAMAGES WHATSOEVER, AND OUR LIABILITY UNDER NO CIRCUMSTANCES WILL EXCEED THE CONTRACT PRICE FOR THE GOODS FOR WHICH THE LIABILITY IS CLAIMED.

IN ORDER FOR THE WARRANTY TO BE EFFECTIVE, THE WARRANTY CARD MUST BE SIGNED AND SENT TO NOVA BIOMEDICAL, 200 PROSPECT ST., WALTHAM, MASSACHUSETTS, USA.

INSTRUCTIONS

1. [redacted] OUT COMPLETELY.
2. In order for the Warranty to be effective, the warranty card must be signed and dated as of the date of delivery and sent to NOVA BIOMEDICAL, WALTHAM, MASSACHUSETTS.
3. Retain the customer copy for your files.

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES

BUSINESS REPLY CARD
FIRST CLASS PERMIT NO. 47966 WALTHAM, MA

POSTAGE WILL BE PAID BY ADDRESSEE

[redacted]

NOVA Biomedical
200 Prospect Street
Waltham, MA 02254-9141